

EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

- - - - - x
IN RE:
VALSARTAN, LOSARTAN, MDL No. 2875
and IRBESARTAN PRODUCTS
LIABILITY LITIGATION

- - - - - x

PARTICIPANTS APPEARING VIA ZOOM

VIDEO DEPOSITION of DAVID MADIGAN, PhD
Thursday, August 5, 2021 - 9:32 a.m.

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I N D E X

WITNESS:

DAVID MADIGAN

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P R O C E E D I N G S

THE VIDEOGRAPHER: Good morning. We are on the record. This is the videographer speaking, Bob Giannini, with court reporter Jill Ruggieri, with Veritext Legal Solutions.

Today's date is August 5, 2021, and the time is 9:32 a.m. We are here to take the remote video deposition of Dr. David Madigan in the matter of In Re: valsartan, Losartan, et al.

Will counsel please introduce themselves for the record.

MR. NIGH: This is Daniel Nigh for the plaintiffs.

MS. LOCKARD: Victoria Lockard is here for Teva defendants as well as for the joint defense.

THE VIDEOGRAPHER: Okay. Thank you.

Will the court reporter please swear in the witness.

DAVID MADIGAN, PhD, a witness

1 having been duly sworn, on oath deposes and
2 says as follows:

3
4 EXAMINATION

5 BY MS. LOCKARD:

6 Q Good morning, Dr. Madigan.

7 A Good morning, Ms. Lockard.

8 Q We just met a few minutes ago.

9 A Yes.

10 Q I represent the Teva defendants in
11 the valsartan litigation in which you've
12 given an expert report.

13 I'll be asking you some
14 questions today. We are off with a bang. It
15 might be fizzled, so I apologize for the
16 short delay here.

17 Do you have everything you
18 need to get started?

19 A I believe so, yes.

20 Q What's your name, sir?

21 A David Madigan.

22 Q Where do you live?

23 A Brookline, Massachusetts.

24 Q What do you do for a living?

25 A I'm the provost at Northeastern

1 University.

2 Q What's your work address?

3 A I don't know.

4 Q Do you maintain an address at the
5 university as well as a separate address for
6 consulting purposes?

7 A I don't have an address for
8 consulting purposes per se.

9 Q Where do you receive your
10 correspondence and invoices for expert
11 witness services?

12 A My home.

13 Q And what profession do you consider
14 yourself a member of?

15 A I'm a statistician.

16 Q What's the difference between
17 biostatistician and statistician?

18 A So biostatistician is a type of
19 statistician who is primarily focused on
20 issues related to, broadly speaking,
21 healthcare.

22 Q Are there any degrees or
23 certifications that entitled you to call
24 yourself a biostatistician?

25 A There's certainly PhD programs and

1 master's degrees as well in biostatistics.

2 That -- sure. Have I answered the question?

3 Q Sure, I think so.

4 Do you have any of those
5 master's degrees or advanced degrees in
6 biostatistics?

7 A I do not.

8 Q All right.

9 You and I have never met
10 before today, correct?

11 A Correct.

12 Q All right.

13 And you understand you're
14 testifying under oath here, sworn to give
15 truthful and accurate testimony, correct?

16 A Yes.

17 Q All right.

18 And do you agree to tell the
19 truth today?

20 A I do.

21 Q Okay.

22 To that end, is there anything
23 that's preventing you today from providing
24 complete and accurate testimony?

25 A No.

1 Q Are you taking any medications or
2 drugs that could affect your memory,
3 comprehension or ability to accurately
4 testify today?

5 A No.

6 Q Do you have any personal
7 limitations on your time today?

8 A I have a dinner reservation at
9 6:45.

10 Q I will -- I will do what I can to
11 keep you on track, but I can't make any
12 promises. All right.

13 Would -- I can't profess to
14 have any sort of degree in statistics, so
15 there's the likelihood that I may ask some
16 questions that are not understandable.

17 If I ask a question that you
18 don't understand, I want you not to answer
19 it.

20 Will you agree to that?

21 A Sure.

22 Q All right.

23 And if you don't understand,
24 would you ask me to rephrase it?

25 A Sure.

1 Q And if you don't ask me to rephrase
2 or reask the question, I'm going to assume
3 you understood it fully.

4 A Fine.

5 Q All right.

6 What were you hired to do in
7 this case?

8 A So I was hired to perform a
9 statistical analysis to evaluate the strength
10 association, dose response and increased risk
11 of certain cancers related to exposure to
12 NDMA and/or NDEA.

13 Q And I understand your opinion is
14 limited to the area of statistics, correct?

15 MR. NIGH: Form objection.

16 A Statistics and/or epidemiology.
17 It's kind of fuzzy where one begins and the
18 other ends.

19 Q All right.

20 So you intend to give
21 epidemiology opinions in the case.

22 A That not what I said. So I have
23 opinions. They're clearly stated in my
24 report. Some of these are -- they're all
25 statistical in nature but some of them

1 pertain to what people would generally call
2 epidemiology studies.

3 Q You feel that you're qualified to
4 give an opinion in this case as to whether or
5 not nitrosamine impurities in the valsartan
6 at issue caused or has the potential to cause
7 cancer in humans?

8 MR. NIGH: Form objection.

9 A I don't offer such opinions. Am I
10 qualified to do so? Probably not. I don't
11 understand enough about the mechanisms and so
12 on. The non-statistical issues.

13 Q Okay.

14 And just -- so to be clear,
15 then, you're not here to offer testimony as
16 to whether or not the nitrosamine impurities
17 in the valsartan medications at issue cause
18 or have the potential to cause cancer in
19 humans?

20 A Correct, I'm not offering a
21 causation opinion.

22 Q Okay.

23 And you will not be offering a
24 causation opinion at trial or at any Daubert
25 hearing in this case, correct?

1 A I don't expect to do so, no.

2 Q And you don't intend to offer any
3 testimonial evidence as to how the
4 nitrosamines formed in medications, I assume?

5 A No.

6 Q And I would refer to that generally
7 as root cause testimony, but you're not
8 giving any root cause testimony as to how the
9 nitrosamines were detected or formed; is that
10 fair?

11 MR. NIGH: Form objection.

12 A I don't think so. Root cause, I'm
13 not entirely sure what you mean by that, but
14 I'm not offering opinions pertaining to the
15 matters you just described.

16 Q All right.

17 You've been deposed a number
18 of times, right?

19 A Right.

20 Q And in each of those times, was
21 your testimony truthful and accurate at the
22 time you testified?

23 A Yes.

24 Q Are you aware as you sit here today
25 of any testimony in prior depositions that is

1 no longer accurate?

2 MR. NIGH: Form objection.

3 A I am not.

4 Q Okay.

5 How long have you been in the
6 practice of expert witnessing?

7 A About 15 or 16 years.

8 Q How did you first get involved in
9 legal consulting?

10 A So I was asked to help with the
11 Vioxx case.

12 Q Okay.

13 So was Vioxx your first
14 litigation?

15 A Yes.

16 Q How many times have you been
17 deposed in total?

18 A I don't know.

19 Q You don't keep a running list
20 beyond four years?

21 A I don't.

22 Q And out of the total depositions
23 you've given, how many of those were as a
24 paid expert? All of them?

25 A Probably. I don't recall, but

1 probably.

2 Q So you've never testified as a
3 defendant yourself, correct, been sued?

4 A Oh, no.

5 Q Okay.

6 Have you ever -- have you ever
7 given a deposition testimony in another
8 context, divorce, you know, personal contract
9 dispute, anything outside of your expert
10 witness testimony?

11 A I don't think so.

12 Q And in each of the cases where you
13 have provided expert witness testimony in a
14 deposition, is it fair to assume that in each
15 of those cases, you have testified as a
16 statistician?

17 A As a statistician and/or
18 epidemiologist.

19 Q But you don't maintain yourself as
20 an epidemiologist, correct?

21 A No, I do.

22 Q Okay. You do? You do believe that
23 you're qualified to speak on epidemiology?

24 A On certain aspects of epidemiology.
25 I'm not qualified to testify about, you know,

1 outbreaks of Listeria or something like that,
2 but in terms of statistical matters
3 pertaining to epidemiology, I am qualified.

4 Q Other than statistics or
5 epidemiology, have you ever given any expert
6 testimony on areas outside of those two?

7 A I don't think so.

8 Q And of all the depositions you've
9 given, do you have a percentage as to which
10 ones were for the plaintiff versus the
11 defendants?

12 A They're mostly for plaintiffs.
13 There were one or two for defense.

14 Q So the vast majority of your expert
15 witness work is for plaintiffs, correct?

16 A That is correct.

17 Q Have you ever been a party to a
18 lawsuit?

19 A I don't think so, no.

20 Q Okay.

21 How many times have you
22 testified at trial total?

23 A I don't know.

24 Q Don't keep a list of trial
25 testimony?

1 A No.

2 Q Do you keep your transcripts from
3 prior depositions/trials?

4 A Not systematically. I -- sometimes
5 I'm sent them. Sometimes I'm not.

6 Q So at -- your work that you do for
7 expert witnessing, do you do that on a home
8 computer or --

9 A Yeah.

10 Q Okay.

11 Do you do any of your expert
12 witnessing work, review or research at
13 university on their computers?

14 A No.

15 Q Did you use a laptop or a home
16 computer?

17 A A laptop.

18 Q And so on your laptop, do you
19 have -- do you keep files regarding each of
20 your cases?

21 A Not necessarily. And so certainly
22 for valsartan right now, I have copies of the
23 papers that I reviewed as well as a copy of
24 my report, but once cases -- as I've worked
25 on a matter that is over, that is finished, I

1 don't keep materials.

2 Q After the case is concluded, do you
3 delete your prior materials?

4 A Generally. Sometimes I'm
5 instructed to do so, but generally, I do.

6 Q What about your -- all of your
7 expert reports? Do you maintain all of
8 those, a copy of those, prior expert reports?

9 A Not systematically. You know, I'm
10 sure I have some of them, but I don't
11 systematically have a place where I keep them
12 all.

13 Q What about unsystematically, do
14 you --

15 A I'm sure I have some of them. Do I
16 have all of them? I doubt it.

17 Q Do you have a hard copy filing
18 cabinet where you keep things like deposition
19 testimony or expert reports?

20 A No.

21 Q Do you have anybody who helps you
22 with your -- the management of your
23 consulting business, like an assistant or
24 manager, family member?

25 A No.

1 Q So it's all you in terms of getting
2 the retentions, getting the letters, if you
3 get any letters, correspondence from counsel,
4 invoices out, all that kind of paperwork you
5 do yourself personally?

6 A Insofar as there's paperwork, I do
7 it myself.

8 Q And I know that was a terrible
9 question, but...

10 A How was my answer?

11 (Laughter.)

12 Q I just -- I think we understand
13 each other. Okay.

14 Do you have any scheduled
15 trial testimony presently?

16 A I do.

17 Q What case is that?

18 A I'm supposed to testify in a
19 Taxotere case. I think it's in November or
20 something like that.

21 Q Okay.

22 Which -- do you recall which
23 case? The plaintiff's name?

24 A No.

25 Q Where is that pending?

1 A New Orleans.

2 Q And you've been deposed I think
3 four times in the Taxotere litigation? Does
4 that sound about right?

5 A Sure.

6 Q Have you ever testified at trial
7 for defense?

8 A I don't think so. There have been
9 a couple of depositions, but I don't think
10 I've given trial testimony on behalf of
11 defendants.

12 Q In the couple of depositions you've
13 given, who was the defendant you testified
14 for?

15 A I'd need to look at my list of
16 testimony. The two in particular were patent
17 cases.

18 Q So you do patent work -- or -- let
19 me strike that.

20 So you do testify as an expert
21 in patent cases?

22 A I have done so.

23 Q So do you testify at Markman
24 hearings before the court?

25 A What was the word?

1 Q A Markman hearing?

2 A That doesn't mean --

3 Q A claim construction hearing for
4 patent cases.

5 A Given that I don't know what that
6 is, I guess the answer is no.

7 Q Have you given live testimony at a
8 Daubert hearing in litigation?

9 A In litigation in general, yes, I
10 have.

11 Q Okay.

12 How many times have you given
13 live testimony in a Daubert hearing?

14 A I don't know. Not many. Maybe
15 three or four, something like that.

16 Q Do you keep a list of your Daubert
17 testimony -- strike that.

18 Do you record all of your
19 Daubert testimony in the last four years on
20 your testimonial list?

21 A Yes.

22 Q I only saw one on here, I believe,
23 in the last four years, and that was in the
24 Abilify litigation.

25 A Yeah.

1 Q So was that -- you believe that's
2 accurate -- let's just make this an exhibit.

3 MS. LOCKARD: This is
4 Exhibit 1 to David Madigan's deposition, this
5 will be the deposition and trial testimony,
6 last four years, and this was Appendix 2 to
7 the expert's report.

8 (Exhibit 1 marked for
9 identification.)

10 BY MS. LOCKARD:

11 Q I'm sorry -- extreme closeup to
12 everybody on the Zoom.

13 All right. So, I mean, you're
14 welcome to look over it, but the only one I
15 saw on -- for Daubert testimony was the first
16 one, which was Abilify.

17 MR. PELTA-HELLER: I'm sorry,
18 what was the name of that file?

19 MS. LOCKARD: Abilify,
20 A-B-I-L-I-F-Y.

21 And for the record, the
22 concierge is with the court reporter -- court
23 reporter's office. Not my personal
24 concierge.

25 A Sorry. So the question was is the

1 Abilify litigation the only one where I
2 appear to have testified in a Daubert
3 hearing?

4 Q In the last four years.

5 A In the last four years, that
6 appears to be the case, yes.

7 Q And I understand some of your
8 testimony was limited in that litigation; is
9 that right?

10 MR. NIGH: Form objection.

11 A I don't recall. I don't recall
12 exactly. Certainly the bulk of my opinions
13 were allowed.

14 Q Okay. So we'll -- we'll come back
15 to some of this.

16 Have you been asked to testify
17 in any Daubert hearing in this case?

18 A No.

19 Q If asked, would you be available to
20 do so?

21 A Yes.

22 Q All right.

23 So the Exhibit 1 that we
24 marked, is this a true and accurate list of
25 testimony that is required under the federal

1 rules, for the last four years?

2 A Yes, that's my intention.

3 Q And the last one on this list
4 appears to be June 15, is the last deposition
5 given?

6 A Oh, there's a June 29 on the bottom
7 of page 3.

8 Q Ah, okay. And that's in the Hurley
9 case.

10 A Yes.

11 Q And that's a talc case?

12 A Yes.

13 Q All right.

14 So any other testimony you've
15 given since you prepared this report that
16 needs to be added to bring it up to date?

17 A No.

18 Q On this list, I counted six trials
19 in the last four years.

20 Is that accurate?

21 A If you say so, I didn't read --

22 Q If the paper says six trials, then
23 you stand by that, right?

24 A I do, yes.

25 MR. NIGH: Form objection.

1 Q And I counted 55 depositions in
2 four years.

3 A Yes, of which the vast majority are
4 talc, yes.

5 MR. NIGH: Form objection.

6 Q Okay.

7 And so in the last for years,
8 it appears that you are averaging about one
9 deposition per month?

10 A Sure.

11 Q How many expert reports would you
12 say you prepare in an average year?

13 A Two or three.

14 Q And are there cases you review but
15 in which you don't give a report or
16 testimony?

17 A Has that ever happened? Maybe. I
18 can think of one case. But in general, no,
19 I'm -- I'm asked to write a report.

20 Q And can you recall any occasions
21 where you were approached to give an opinion
22 and you turned down the case for whatever
23 reason?

24 A Oh, yeah. If I'm not -- if it's
25 outside the scope of my expertise, obviously

1 I won't do it.

2 Q But you -- can you think of any
3 case in which you were asked to give any
4 opinions within the areas of statistics or
5 epidemiology that you turned down?

6 MR. NIGH: Form objection.

7 A Not that I can recall. I'm asked
8 in each case to do certain analysis, and if
9 it's within my capability to do those
10 analyses, I do them, I write a report.

11 Q Why do you think it is that your --
12 most of your work is on behalf of plaintiffs?

13 MR. NIGH: Form objection.

14 A I don't know. I'm not asked to
15 be -- I don't have any -- it's not a bias on
16 my behalf. I'm just never asked. That's the
17 correct answer to your question. I'm not
18 asked.

19 Q What percentage of your
20 professional time is spent consulting on
21 legal matters?

22 A It has ebbed and flowed over the
23 years. Currently, it's modest. It's 10
24 or -- 10 percent, 15 percent, something like
25 that.

1 Q And that's 10 percent of your
2 professional time is spent on litigation
3 consulting; is that right?

4 A Yes.

5 Q Okay.

6 What's the other 90 percent
7 spent on?

8 A I have a day job.

9 Q Okay.

10 You're professor at a
11 university? Is that the other 90 percent?

12 A Well, and I'm provost, yes.

13 Q And provost.

14 How does that -- the other 90
15 percent split between provost and professor?

16 A There's no daylight between those
17 two things. The role is -- I am --
18 primarily, I work -- my work pertains to
19 being a provost. I'm not in the classroom
20 much at the moment, for instance.

21 Actually, just to give you a
22 complete answer, I also do other types of
23 consulting outside of litigation.

24 Q All right.

25 So we've got 10 percent that's

1 litigation consulting. Okay. Out of the
2 remaining 90 percent, how much of that is
3 non-litigation consulting?

4 A Maybe 5 percent.

5 Q And what kind of things are those?

6 A There's a list in my CV. I've
7 consulted for many pharmaceutical companies
8 over the years.

9 Q Clinical trial work, grants, things
10 of that nature?

11 A No.

12 Q No grants?

13 A No, grants would be at the
14 university. I've also consulted for Boeing
15 for 10 years, I was a consultant to Boeing,
16 involved in all kinds of different things.

17 There's a list in my CV. It's
18 a long list.

19 Q And we'll pull that up and make it
20 an exhibit in a few minutes.

21 Okay.

22 So that's 15 percent accounted
23 for. So is the other 85 percent associated
24 with your duties at the university?

25 A Yes.

1 Q Any other professional activities
2 that you're engaged in other than what we've
3 already talked about, currently?

4 A No, nothing that's not related to
5 my job at the university.

6 Q Do you have any plans to retire
7 anytime soon?

8 A No.

9 Q Any plans to change jobs, change
10 universities, move?

11 A No.

12 Q In the cases that -- where you
13 mentioned that you had served as an expert
14 witness for defendants, do you recall if
15 those were in pharmaceutical cases?

16 A We could look at the list. I think
17 one of them -- as I said, they're
18 intellectual property matters. They were
19 pertaining to drugs.

20 Q Were they in the last four years?

21 A No, probably not.

22 Q So they're not on your Exhibit 1?

23 A Good point. Yeah, they're probably
24 not. They're not, I'm sure. I don't think.
25 I have to check. Let me see.

1 (The deponent read the
2 document.)

3 Right. They're more than four
4 years ago.

5 Q Okay.

6 Do you recall if those cases
7 were for pharmaceutical companies?

8 A Yes, they were.

9 Q Do you recall which companies?

10 A No.

11 Q Are you aware of who the defendants
12 are, the named manufacturer defendants, in
13 this litigation?

14 A In this litigation?

15 Q Yes.

16 A No. I understand Teva is one of
17 them. I don't know about the other ones.

18 Q All right.

19 So you haven't reviewed any
20 Teva documents, though, as I understand.

21 Is that correct?

22 A I don't know. So my hesitation is
23 I cite to a couple of documents, footnote 6
24 and footnote 7. I don't think they're Teva
25 documents. I think Torrent is another

1 defendant. And I'm not sure about footnote
2 6.

3 Q We'll talk more about the materials
4 in a little bit.

5 Okay. What percentage of your
6 income is from expert witnessing versus the
7 other 90 percent?

8 MR. NIGH: Form objection.

9 A I don't know exactly, but it's
10 probably around 20 percent.

11 Q Do you report all of your expert
12 witnessing income to the IRS?

13 A I do.

14 Q Have you ever been audited by the
15 IRS?

16 A No.

17 Q Do you have to give any portion of
18 your income from expert witnessing to the
19 university?

20 A No.

21 Q Do you make it a practice to donate
22 or give any certain portion of your expert
23 witnessing funds to any charities?

24 A No, not since -- I have done but I
25 don't do it systematically.

1 Q Do you know how many matters --
2 litigation matters you have right now that
3 are open matters that you're consulting on?

4 MR. NIGH: Form objection.

5 A Four, maybe.

6 Q And are those talc, Taxotere,
7 valsartan, and what's the other one?

8 A I wasn't actually counting
9 valsartan, but Zostavax and Combat Arms
10 Earplug.

11 Q 3M?

12 A 3M.

13 Q To your knowledge, have you ever
14 been retained by Teva in any consulting
15 capacity?

16 A Not to my knowledge.

17 Q Have you ever been retained by
18 Mylan in any consulting capacity?

19 A No.

20 Q Ever retained by Hetero in any
21 consulting capacity?

22 A I don't think so.

23 Q Ever retained by Torrent in any
24 consulting capacity?

25 A I don't think so.

1 Q Ever retained by Aurobindo in any
2 consulting capacity?

3 A No, I don't think so.

4 Q Ever retained by ZHP, Zhejiang
5 Huahai?

6 A No.

7 Q Ever retained by Solco or Princeton?

8 A No.

9 Q Are you -- strike that.

10 Have you ever paid to be
11 listed in any expert witness database or
12 service?

13 A No.

14 Q Do you know if you're listed on any
15 publicly available expert witnessing
16 databases, paid or not?

17 A I don't think so.

18 Q Have you ever testified in any
19 litigation pending outside of the United
20 States?

21 A I have.

22 Q Where was that?

23 A I testified in Canada. I testified
24 in Australia.

25 Q Were those --

1 A I think that's it.

2 Q Were those in product liability
3 cases, like most of what's on your report?

4 A Yes.

5 Q Have you ever spoken to or given a
6 presentation to a group of lawyers, like the
7 ABA or a trial lawyers association?

8 A No, I don't think so, although I am
9 scheduled to do so this fall in a continuing
10 legal education context.

11 Q What -- who's the sponsor of that
12 seminar?

13 A I have no idea.

14 Q When is it taking place?

15 A Sometime this fall.

16 Q Can you be more specific?
17 September, October, November?

18 A Don't know. I think it's --
19 actually, it's being scheduled. I know
20 there's to-ing and fro-ing right now about
21 the scheduling.

22 Q Is it an in-person seminar?

23 A Don't know.

24 Q Who asked you to participate?

25 A I'm giving it, so I'm doing it with

1 myself and a lawyer are preparing a session
2 on -- on biostatistics.

3 Q Who's the lawyer?

4 A His name is Abe Alexander.

5 Q And is it focused on any particular
6 litigation?

7 A No.

8 Q Do you know who the audience is?

9 A No.

10 Q Do you know where it's supposed to
11 take place?

12 A No.

13 Q How much money did you make last
14 year from serving as an expert witness in
15 litigation?

16 A I don't know.

17 MR. NIGH: Form objection.

18 Q Do you have tax records that would
19 show that?

20 A Yes.

21 Q Have you ever had to produce your
22 tax records in any expert capacity in
23 litigation?

24 A No.

25 Q Do you know how much money you've

1 made this year, in 2021, from serving as an
2 expert witness?

3 A No.

4 Q How do you --

5 MR. NIGH: Form objection.

6 Q How do you bill for your time spent
7 expert witnessing?

8 A I just keep track of my hours and
9 just periodically bill.

10 Q Is it -- do you do monthly invoices
11 or just as-needed?

12 A It's when I think of it.

13 Q Do you keep time sheets?

14 A I keep a running -- you know, I
15 keep track on an invoice. I start to open an
16 invoice, and as I spend time on a matter, I
17 add it to the invoice.

18 Q On an electronic document?

19 A Yes.

20 Q All right.

21 What's the billing arrangement
22 that you require when you're retained on a
23 case? Is there a retainer?

24 A No, I don't do retainers.

25 Q All right.

1 Do you have any special
2 riders/requirements?

3 A No. I don't think so. Like, I'm
4 not sure what that would be.

5 Q Like, you know, special provisions
6 if you have to stay in certain hotels or a
7 per diem if you're testifying out of -- you
8 know, out of your home state?

9 A No.

10 Q So the deal is, you just bill
11 monthly for your time?

12 A I didn't say monthly. I keep track
13 of my hours.

14 Q Okay.

15 A And from time to time I tally it up
16 and send it to the attorney.

17 Q You're correct. I completely
18 misspoke on that. I meant to say you just
19 bill hourly for your time?

20 A Yes.

21 Q Do you charge \$800 per hour for
22 your work in this case; is that right?

23 A Yes.

24 Q And is that what you'll charge if
25 you testify at trial?

1 A Sure.

2 Q And that's whether it's all day,
3 two days, three days, it's 800 an hour?

4 A It's for time worked, so it would
5 be hours I spend on the stand.

6 Q You don't charge getting to trial
7 or returning travel?

8 A I do not.

9 Q Do you bill expenses back to the
10 firm?

11 A If there are any, I would, yeah,
12 direct expenses.

13 Q Do you have any retention letter or
14 consulting agreement that you use typically?

15 A No.

16 Q Is there any retention letter in
17 this case?

18 A I don't think so.

19 Q Any consulting agreement entered in
20 this case?

21 A No.

22 Q Do you also charge \$800 an hour for
23 Daubert hearing time?

24 A For time spent actually testifying,
25 yes.

1 Q Do you know how much you've billed
2 in total on this case?

3 A I don't, but you have the invoices.

4 Q Okay.

5 Let's take a look at those.

6 These were invoices produced
7 as part of your file yesterday, so I don't
8 know if everyone on the Zoom received these.

9 MS. LOCKARD: Let me ask you,
10 Mr. Nigh, do you know if those were sent out
11 broadly to the defendants or were they
12 just --

13 (Unidentified voice.)

14 (Reporter clarification.)

15 MR. BOGDAN: It's Rosemarie.

16 THE VIDEOGRAPHER: Do you want
17 to go off the record?

18 MS. LOCKARD: You can keep the
19 camera rolling.

20 (Discussion off the record.)

21 MS. LOCKARD: We can go back
22 on the record, please.

23 BY MS. LOCKARD:

24 Q All right, Dr. Madigan.

25 So I have in my hands the

1 invoices that were produced by counsel for
2 plaintiffs yesterday. I received four of
3 them.

4 Do you know if you've sent out
5 more than four invoices in the valsartan
6 litigation?

7 A I have not.

8 Q Okay.

9 Now, I'm going to just go
10 through these one at a time.

11 The first one -- this will be
12 Exhibit 2. The first one is dated March 1,
13 2020.

14 (Exhibit 2 marked for
15 identification.)

16 BY MS. LOCKARD:

17 Q And is that a true and accurate
18 copy of your invoice in the valsartan
19 litigation?

20 A Yes.

21 Q It looks like it was addressed to
22 Ned McWilliams.

23 Do you know who Ned McWilliams
24 is?

25 A He's an attorney.

1 Q Is he with Mr. Nigh's firm?

2 A I don't know. I think he is.

3 Q Has he been your primary contact on
4 the case so far?

5 A No.

6 Q Who has been?

7 A Mr. Nigh, and Ms. Bogdan.

8 Q All right.

9 So if we look at this invoice,
10 this is a March 1, 2020 invoice. This
11 appears to be your first invoice sent out in
12 the case.

13 Is that correct?

14 A Yes.

15 Q And it looks like you billed for
16 eight and a half hours at \$800 an hour for a
17 total of \$6,800, correct?

18 A Yes.

19 Q Has this invoice been paid?

20 A Yes.

21 Q All right.

22 So it looks like you had an
23 initial literature review on December 1,
24 2019, was your first work on the case, right?

25 A Yes.

1 Q What did you review in the initial
2 literature review?

3 A I have no idea.

4 Q Do you recall if it was materials
5 sent to you by plaintiffs' counsel or if
6 that's your own literature research review?

7 A Don't recall.

8 Q Did you do independent research in
9 the case during the course of your review?

10 A As against? I don't understand the
11 question.

12 Q Okay.

13 If I reference independent
14 research, I mean you, Dr. Madigan, actually
15 doing a PubMed search or some sort of search
16 in a literature database yourself as opposed
17 to being provided documents by counsel.

18 Do you follow?

19 A Yeah, I do.

20 Q Okay.

21 So assuming that to be the
22 case, did you do any independent research in
23 the case during the course of your review?

24 MR. NIGH: Form objection.

25 A I have done some what you're

1 calling independent research, yes, I've done
2 some work along those lines.

3 Q What databases did you use to
4 perform that research?

5 A So what's coming to mind is, in
6 particular, I looked at -- the Song
7 meta-analysis was done in 2015, so I ran -- I
8 did do a search to see was there anything
9 since then that fit the criteria described in
10 Song.

11 I used the same databases that
12 Song describes, the same search.

13 Q Did your search generate any new
14 material or studies?

15 A It generated -- the search produced
16 a bunch of studies, I don't know, 50 or
17 something, but none of them -- again, I went
18 through them. None of them were -- were
19 appropriate to include, or relevant.

20 Q Why were they not appropriate or
21 relevant to include?

22 A Because they didn't satisfy the
23 criteria --

24 Q What --

25 A -- in Song.

1 Q What was the criteria you were
2 looking for?

3 A You'd need to put Song in front of
4 me. I don't remember.

5 Q Okay. Let's come back to that,
6 then.

7 All right. So -- all right.

8 Any -- other than the search
9 to see if there were any updated results from
10 the Song study, did you do any other
11 independent research in the case?

12 A If you're equating -- if you're
13 equating independent research with searches,
14 then I -- that's the only search I recall
15 doing at this point.

16 MR. NIGH: Form objection.

17 Q All right.

18 So in the initial invoice, it
19 looks like you had a total of four hours,
20 initial literature review. Then you had a
21 phone call, and then you had another four
22 hours of literature review.

23 Is that correct?

24 A Yeah.

25 Q Who did you have the phone call

1 with on December 4?

2 A I don't know.

3 Q Do you know what the purpose of
4 that call was?

5 A I do not.

6 Q Did you take any notes during that
7 call?

8 A No.

9 Q At this point, when you sent this
10 invoice, had you received any letters or
11 correspondence from plaintiffs' counsel?

12 A Letters or correspondence?

13 Q Written letters or written
14 correspondence. Not email.

15 A Oh. No.

16 Q Like old-fashioned US Mail.

17 A I don't know what else I was
18 thinking.

19 Can I ask a question?

20 Q Yes.

21 A There's a question mark on this.
22 That's not mine. I just -- for the record, I
23 just want to --

24 Q I don't know why that's there.

25 A Okay.

1 Q Let's just mark that out. It won't
2 be on the official exhibit.

3 A Okay.

4 Q But thank you. If you see any
5 other stray marks, let me know.

6 A Okay.

7 Q So -- so in the course of this
8 litigation, you don't think you've received
9 any letters through the mail, written
10 correspondence from plaintiffs' counsel; is
11 that right?

12 A I know for a fact I have not.

13 Q Has your communication been through
14 email primarily?

15 A Yes.

16 Q All right.

17 And has your communication
18 with plaintiffs' counsel been through the
19 Levin Papantonio firm, Mr. Nigh's firm?

20 A I guess so.

21 Q Do you recall speaking with any
22 other lawyers on plaintiffs' side in the case
23 outside of Mr. Nigh's firm?

24 A Is Ms. Bogdan with a different
25 firm? I'm not sure.

1 MR. NIGH: Yes, she is.

2 MS. LOCKARD: What firm are
3 you with? I'm sorry.

4 MS. BOGDAN: My office is
5 Martin Harding & Mazzotti.

6 MS. LOCKARD: Martin
7 Harding & Mazzotti.

8 Q So other than Martin
9 Harding & Mazzotti and Levin Papantonio, you
10 don't recall any specific communications with
11 other law firms discussing valsartan.

12 Is that right?

13 A Correct.

14 Q Had you worked with Martin
15 Harding & Mazzotti before this litigation?

16 A I don't think so.

17 Q Okay.

18 So is this the first case
19 you've been involved in with that firm to
20 your knowledge?

21 A As far as I know.

22 Q And have you worked with Mr. Nigh's
23 firm previously on matters?

24 A I think I did work with that firm
25 in the Pradaxa litigation, I think.

1 Q Are you familiar with plaintiffs'
2 attorney Adam Slater, who is involved in the
3 litigation?

4 A No.

5 Q To your knowledge, have you ever
6 worked with Adam Slater or the firm Mazie
7 Slater?

8 A Not to my knowledge.

9 Q Have you -- are you familiar with
10 David Stanoch?

11 A No.

12 Q Ever worked with David Stanoch or
13 his firm, to your knowledge?

14 A Not to my knowledge.

15 Q Are you familiar with an attorney
16 by the name of Ruben Honik?

17 A No.

18 Q Ever worked with Ruben Honik or his
19 firm?

20 A No.

21 Q Familiar with a Conlee Whiteley?

22 A No.

23 Q Ever worked with her firm?

24 A No.

25 Q I'm missing somebody. I don't mean

1 to leave them out.

2 All right. Let's get back to
3 the invoice.

4 Okay. So you don't have any
5 knowledge of what you reviewed in December of
6 2019.

7 A I do not.

8 Q Okay.

9 And you don't have any record
10 of what you were sent in your original
11 package from plaintiffs' counsel; is that
12 right?

13 MR. NIGH: Form objection.

14 A I never said there was an initial
15 package. I just don't recall.

16 Q Okay.

17 Was there an initial package
18 that came from plaintiffs when you were
19 retained?

20 A Not in the mail. Did they send me
21 some papers at the outset? I don't remember.

22 Q So typically when you're retained,
23 are there certain things you ask for, like
24 complaint or depositions or things of that
25 nature, or do you leave it to the attorneys

1 to decide what's sent to you?

2 MR. NIGH: Form objection.

3 A So it all depends. If -- in this
4 particular case, I was asked to do an
5 analysis of a particular set of studies, and
6 that's what I did.

7 Q And so when you were asked to do
8 the analysis of that particular set of
9 studies, did plaintiffs' counsel provide
10 those studies to you?

11 MR. NIGH: Form objection.

12 A I don't recall the exact sequence
13 of events.

14 Q All right.

15 So I will mark as Exhibit 3
16 the next invoice in the case. And this is an
17 invoice dated July 26, 2020.

18 (Exhibit 3 marked for
19 identification.)

20 BY MS. LOCKARD:

21 Q Does that appear to be a true and
22 correct copy of your invoice?

23 A Yes.

24 MR. NIGH: Can I see it?

25 (Counsel read document.)

1 MS. LOCKARD: And for the
2 record, for the court reporter, he probably
3 needs to have his Social Security/tax number
4 redacted.

5 MR. NIGH: Absolutely.

6 BY MS. LOCKARD:

7 Q Okay.

8 So this invoice appears to
9 have the total hours of 19 hours. And were
10 you charging \$800 at the time?

11 A Yes.

12 Q All right.

13 So the total invoice amount is
14 \$15,200, correct?

15 A Yes.

16 Q Has that been paid?

17 A Yes.

18 Q All right.

19 So it looks like again during
20 the period March 2020 to May 2020, you were
21 doing some additional literature review, you
22 had one call, and then you did an NDEA
23 review, correct?

24 A Yes.

25 Q What is meant by NDEA review?

1 A I don't recall.

2 Q When you were first retained in the
3 case, what were you told about what
4 nitrosamines were or what they were -- or
5 which ones were at issue?

6 MR. NIGH: I'm actually going
7 to instruct him not to answer. Seeking
8 attorney-client privilege.

9 Q Let me ask it this way: When you
10 were first retained, were you asked to give
11 any opinions regarding NDEA studies?

12 A I was certainly asked to give
13 opinions about NDMA and NDEA, but
14 specifically the way you asked it there was
15 at the outset. I don't recall whether I was
16 asked that right at the outset or if that was
17 added later, I don't remember.

18 Q Yeah, I mean, it -- the conclusion
19 that I drew from reviewing Exhibit 3 is that
20 in May of 2020, it appeared that the NDEA
21 issue was raised or called to your attention.

22 Does that seem like a fair
23 conclusion from the documentation?

24 MR. NIGH: Form objection.

25 A It's a speculation. I just don't

1 know.

2 Q All right.

3 And you don't recall what
4 literature review you did or whether it was
5 provided to you by counsel?

6 A I don't remember.

7 Q And when you keep notes of your
8 time, you don't keep any more detailed notes
9 other than just this two-word entry,
10 "literature review"?

11 A Correct, I do not.

12 Q Do you know who the call was with
13 on March 20th?

14 A I don't.

15 Q Do you recall what was the purpose
16 of the call?

17 A I do not.

18 Q Let's take a look at the next
19 invoice, which we'll mark as Exhibit 4. And
20 it's dated April 17, 2020.

21 (Exhibit 4 marked for
22 identification.)

23 BY MS. LOCKARD:

24 Q Does this look like a true and
25 correct copy of your invoice in this case?

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1 A Yes.

2 MR. NIGH: Can I see a copy.

3 (Counsel read document.)

4 Q And this invoice is for 20.5 hours
5 at \$800, and you billed 16,400.

6 A Correct.

7 Q And was this invoice paid?

8 A Yes.

9 Q Is your payment coming from the
10 Levin Papantonio firm?

11 A I don't know.

12 Q You don't know who the check is
13 from?

14 A Sitting here this minute, I don't
15 know, yeah.

16 Q So in terms of the work that was
17 done during this period -- let me ask you
18 this: So you look at the date of this
19 invoice is April 17, 2020. However, the
20 first --

21 A That should be 2021. That's an
22 error.

23 Q Okay.

24 A Yeah.

25 Q So invoice which is Exhibit 4

1 should actually -- it has an error on the
2 date, correct?

3 A Yeah, yeah.

4 Q All right.

5 So we can assume this is
6 actually sent on April 17, 2021, correct?

7 A Yes.

8 Q So if you look at the work that was
9 done there, there's a call, and then there's
10 the word "analysis."

11 What do you mean by "analysis"
12 in your billing records?

13 A I don't know. I was in -- it just
14 means I was doing work. I was doing an
15 analysis, whether it means I was reading
16 papers, doing any kind of statistical
17 calculation, it's nonspecific.

18 Q Okay.

19 So is it going to be
20 interchangeable with review of materials or
21 does it indicate you're actually doing some
22 sort of calculations?

23 A It's ambiguous.

24 Q All right.

25 So the word "analysis" on here

1 is ambiguous? You can't provide us any more
2 information about that?

3 A I can't.

4 Q Okay.

5 It looks like from this
6 document that your report was actually
7 started on April 4.

8 Is that right?

9 A So it seems, yeah.

10 Q Okay.

11 So when you start your report,
12 is that when you actually -- you open up the
13 document and start drafting the text of the
14 report?

15 A It might have been. I can't be
16 certain I didn't do that earlier.

17 Q We don't see anything on your
18 invoice related to a report before April 4,
19 2021.

20 A We do not, but that doesn't mean
21 that I wasn't doing it.

22 Q Okay.

23 So it looks like at this point
24 in time, on April 4, it looks like you -- if
25 you look at the three invoices, you had spent

1 four hours reviewing documents, less than ten
2 hours on analysis, and 15 hours on literature
3 review.

4 A Okay. If you say so.

5 Q And one hour on NDEA.

6 Is that accurate?

7 A Three. Three.

8 Q So it's not accurate?

9 A You said one. It's three. Right?

10 Q All right.

11 So you had -- at that point in
12 time, you had spent -- let me get it.

13 When you started the report,
14 you had some phone calls, you had spent three
15 hours on NDEA review, you had spent four
16 hours on reviewing literature, less than ten
17 hours on analysis, and another 15 hours on
18 literature review.

19 Is that correct?

20 A I mean, I --

21 MR. NIGH: Form objection?

22 A -- if you want me to do the
23 arithmetic -- I don't doubt you're doing it
24 right, but...

25 Q But any work you'd done up until

1 that point on April 4, 2021 is reflected in
2 your invoices?

3 A April 14, 2021, yes, it is.

4 Q But any work that you've done on
5 the case up until April 4, 2021, is reflected
6 on these invoices?

7 A Why are you saying 4th? 14th.

8 Q Your invoice says April 4th is when
9 you started your report.

10 A Oh, sorry, I'm not following what
11 you're talking about.

12 No, I'm not sure that's the
13 date I started my report.

14 Q Okay.

15 But any work that you did
16 prior to April 4 is going to be documented on
17 your invoices, right?

18 MR. NIGH: Form objection.

19 A Sure.

20 Q Okay.

21 Let's look at the fourth and
22 final invoice. This will be Exhibit 5.

23 (Exhibit 5 marked for
24 identification.)

25 BY MS. LOCKARD:

1 Q Okay.

2 And this was dated July 18,
3 2021. And is this a true and correct copy of
4 your fourth invoice?

5 A Yes.

6 Q And you billed for 50 hours at \$800
7 an hour for a total of \$40,000, correct?

8 A Yes.

9 Q And if you add up the prior
10 invoices plus this one, and you can do the
11 arithmetic on this, I would ask you to if you
12 need to, it looks to me like the total
13 bill --

14 (Technical difficulties.)

15 (Reporter clarification.)

16 Q Adding the total of these four
17 invoices, Dr. Madigan, it appears that you
18 have billed and been paid a total of \$78,400
19 in the case so far?

20 A Yes.

21 Q Is that accurate?

22 A Yes.

23 Q And is there any additional work
24 that you've done prior to today that has not
25 been billed?

1 A There are a few hours spent
2 preparing for today.

3 Q How many hours did you spend
4 preparing for today?

5 A I don't recall.

6 Q Did you meet with counsel before
7 today?

8 A Yes.

9 Q Did you meet with counsel
10 yesterday?

11 A Yes.

12 Q How many hours did you spend
13 yesterday?

14 A Couple of hours, something like
15 that.

16 Q Do you have any intention to do
17 additional work on the case prior to any
18 trial or Daubert testimony?

19 MR. NIGH: Form objection.

20 A Not unless I'm asked. Right now, I
21 don't.

22 Q Is there -- are there any materials
23 that you're awaiting to review?

24 MR. NIGH: Form objection.

25 A No.

1 Q When you met with counsel
2 yesterday, was it with both counsel who are
3 present today defending the deposition?

4 A Yes.

5 Q Was anybody else in the meeting
6 with you?

7 A No.

8 (Pause.)

9 Q Do you have any other cases with
10 the Levin Papantonio firm other than the
11 valsartan litigation currently?

12 A Not that I'm aware of.

13 Q Prior to being contacted by the law
14 firm in this case, were you aware of the
15 issue involving nitrosamines in valsartan?

16 A I don't know. I might have read
17 about it. There's a certain amount of
18 publicity.

19 Q But as you sit here today, you
20 don't remember one way or the other if you
21 had seen any publicity on the recall or the
22 issues?

23 A I do not.

24 Q Is it fair to assume you were --
25 you did not take valsartan? You're not a

1 patient who took valsartan?

2 A No, I'm not.

3 Q Okay.

4 Do you do any monitoring of
5 newly filed litigation --

6 A No.

7 Q -- in your office?

8 A No.

9 Q So when you were contacted by
10 plaintiffs' firm in this case you knew you
11 were being contacted on behalf of plaintiffs'
12 counsel.

13 Is that correct?

14 A Yes, probably.

15 Q So you knew you were being asked to
16 review studies that supported the plaintiffs'
17 case from your first interaction.

18 Is that fair?

19 MR. NIGH: Form objection.

20 A No. The way you phrased it was
21 just awkward: I was asked to review studies
22 that were in favor of. No, I was asked to
23 review studies.

24 Q Did you understand that these were
25 studies that plaintiffs had selected for you

1 to review?

2 MR. NIGH: Form objection.

3 A So the set of studies that I
4 included in my analysis are studies that are
5 pursuant to a search that Dr. Etminan did.

6 Q And had you worked on cases
7 involving Dr. Etminan as an expert before?

8 A Not that I can recall. I've never
9 met him.

10 Q So you don't know Dr. Etminan?

11 A I do not.

12 Q And you don't recall ever reviewing
13 any studies that Dr. Etminan had relied on in
14 other litigation?

15 A Reviewing studies that Dr. Etminan
16 had relied on in another litigation. Not
17 that I can recall. I recall using or
18 incorporating one of his studies in a
19 previous litigation, in a report I did in a
20 previous litigation.

21 Q Maybe --

22 A That's not the question you're
23 asking, though. Right? So you're asking a
24 different question.

25 Q Right.

1 The studies that you reviewed
2 in generating your opinions in this case, who
3 selected those studies --

4 MR. NIGH: Form objection.

5 Q -- for review?

6 A So I was asked to review the
7 studies that Dr. Etminan -- that came out of
8 Dr. Etminan's search. They're the ones I
9 reviewed.

10 Now, as we discussed, I did
11 some of my own searching as well. I searched
12 to see was there anything -- any update for
13 Song. I also looked -- as I read through the
14 papers, I looked to see were there references
15 to other studies that were missed. There
16 weren't.

17 Q But every study that is cited in
18 your report is also cited in Dr. Etminan's
19 report.

20 Isn't that right?

21 A That's the way it turned out.

22 MR. NIGH: Form objection.

23 Q Have you reviewed Dr. Etminan's
24 report?

25 A No, I have -- I have the list of

1 studies -- I have the reference list from his
2 report.

3 Q Who provided that to you?

4 A The attorneys.

5 Q Have you ever had any direct
6 discussions with Dr. Etminan?

7 A No.

8 Q Any emails with Dr. Etminan?

9 A No.

10 Q Any in-person contact with
11 Dr. Etminan?

12 A No.

13 Q And even as you sit here today, you
14 still haven't reviewed his report?

15 A I've not seen it.

16 (Pause.)

17 Q In preparing your report or
18 opinions in this case, did you ask for any
19 materials from plaintiffs that were not
20 provided?

21 A No.

22 Q Did you attempt to locate any
23 materials on your own for use in your
24 opinions in your report that you could not
25 locate?

1 A No.

2 Q So have you reviewed any other
3 expert report issued in this case, other than
4 your own?

5 A No.

6 Q Have you in any other litigation
7 ever been provided a collection of literature
8 relied on by another expert and asked to
9 assess that set of literature?

10 MR. NIGH: Form objection.

11 A Not -- I'm not certain. That might
12 have happened in -- I did work on Actos
13 litigation, Actos, years ago. Might have
14 happened in that context. I don't remember.

15 Q So you think you might have been
16 asked in the Actos litigation to -- to review
17 another expert's collection of literature
18 that he or she had relied on?

19 A Yeah, I'm not certain, but I think
20 I might have done that in Actos.

21 Q Do you recall who the expert was?

22 A No. It was a long time ago.

23 Q So other than the Actos, you don't
24 ever recall performing the function that you
25 were asked to perform in this case, which is

1 take a look at these articles that are relied
2 upon by another expert and give us your
3 statistical assessment?

4 MR. NIGH: Form objection.

5 A Are you framing that in litigation?

6 Q Yes.

7 A Okay. Because I've done it in
8 other contexts.

9 In litigation, as I say, I
10 think that's what happened in Actos. There
11 may have been others that I don't recall.

12 Q But you can't recall any other
13 cases as you sit here today, right?

14 A No.

15 Q In what other context have you been
16 asked to do such an exercise?

17 A It's actually something I've done
18 routinely in consulting.

19 Q Consulting for whom?

20 A Pharma companies.

21 Q And that involves they give -- the
22 pharma company gives you a discrete set of
23 literature and says assess the --

24 A Yeah.

25 Q -- statistical significance of

1 these articles?

2 A No. That's putting words in my
3 mouth. It's they hand -- they've said here's
4 a set of studies that are germane to a
5 question we're interested in. Please take a
6 look, and -- and do an analysis with respect
7 to question A, B, and C, whatever the topic
8 might be.

9 Q And in those -- how many times has
10 that happened in a consulting scenario?

11 A I don't know.

12 Q A couple?

13 A Like half a dozen, maybe ten times.

14 Q And in those scenarios, you didn't
15 do any additional research on your own to
16 identify additional articles or literature to
17 review?

18 MR. NIGH: Form objection.

19 A I don't recall specifically, but I
20 can tell you that I fairly routinely have
21 been asked, you know, here's a collection of
22 studies, we're interested in the following
23 question or questions, please analyze them.

24 Q And that's essentially what you
25 were asked to do in this case.

1 MR. NIGH: Form objection.

2 Q Is that right?

3 A Pretty much, yeah.

4 Q Okay.

5 And -- all right. So what was
6 the following question or questions that you
7 were asked to analyze in this case?

8 A I answered that question already.
9 So I was asked -- do you want me to read it
10 again?

11 Q Yes. If that's your answer.

12 A It's the answer. "I was asked to
13 perform a statistical analysis to evaluate
14 the strength of association, dose-response
15 and increased risk of the cancers reported in
16 certain dietary and occupational studies
17 which specifically examined exposure to NDMA
18 or NDEA. Specifically, I considered the
19 studies considered by Dr. Etminan that
20 estimated NDMA or NDEA effect sizes."

21 Q Let's get a copy of your report
22 marked as Exhibit 6.

23 A I do have a correction.

24 Q Yes, let's do that now.

25 I'm going to mark this as

1 Exhibit 6 now. This is a report dated
2 July 7, 2021.

3 (Exhibit 6 marked for
4 identification.)

5 BY MS. LOCKARD:

6 Q Does this look like the --

7 A Yes.

8 Q -- report that was produced in this
9 case?

10 A Yes.

11 Q Okay.

12 Now, I understand from our
13 discussion off the record that you do have
14 some changes you would like to make to your
15 report, correct?

16 A Yes.

17 Q All right.

18 Can you just -- before you
19 make the changes, can you just describe them
20 for the record?

21 A Sure.

22 So one of the studies, it's
23 the Goodman study, gave a -- a milligrams
24 per -- what I thought was milligrams per day,
25 but in actual fact -- which is what's usually

1 provided in these studies, but in fact it was
2 milligrams per week. And I missed that.

3 So the accumulative exposure
4 is therefore seven times too large and needs
5 to be divided by seven.

6 Q Is that the only change or are
7 there others?

8 A No, that's it. It -- it is --
9 impacts a number in three different places in
10 the report. It's the same issue. The one
11 change is in three places.

12 Q Did someone point that error out to
13 you or did you discover it on your own?

14 A All on my own.

15 Q I assume before your testimony,
16 it's your practice to re-review your report,
17 correct?

18 A Yes.

19 Q And as part of that re-review, do
20 you do a careful review to make sure there
21 are no errors or misstatements?

22 A Precisely.

23 Q Okay.

24 And is that what led you to
25 discover this error today?

1 A Yes.

2 Q All right.

3 So are you prepared to make
4 the correction in your report?

5 A Sure. So if you go to page 7,
6 Table 1, go down to Goodman, two entries, so
7 both of those numbers, the 16,363, both of
8 those numbers should be 2,338.

9 Q Okay.

10 How -- what was the cause of
11 this error? Did you misread something in the
12 article or your calculation was erroneous?

13 A So as I just told you, in the
14 paper, what was quoted was milligrams per
15 week, and I mistook that for milligrams per
16 day. Milligrams per week is unusual. I
17 hadn't seen that anywhere else.

18 Q All right.

19 So did you correct the number
20 on that -- here, can you just highlight it
21 with the orange so I can not miss it?

22 A Actually, this is going to make a
23 mess, because it's pink, but anyway.

24 (Deponent complies.)

25 Q Good enough. All right.

1 A And then the two other places that

2 I --

3 Q Yes.

4 A So as a consequence, if you go to
5 paragraph 24 -- I'll highlight it first.

6 Paragraph 24, the number there that is 4,303
7 in paragraph 24 should be 2,338.

8 Q Mm-hmm.

9 A And similarly, the exact same thing
10 in paragraph 33, there's a number there that
11 is 4,303. Same thing. That should be 2,338.

12 Q All right.

13 So can you just make that
14 notation on both of those pages and highlight
15 them?

16 You did. All right.

17 Okay. So with these revisions
18 in mind, does this change your ultimate
19 opinion?

20 A No.

21 Q Okay.

22 And that modification was in
23 paragraph 33 which is part of your conclusion
24 section, correct?

25 A Yeah. I probably answered that

1 other question too quickly. I mean, it
2 doesn't qualitatively change my opinion. It
3 quantitatively changes because the number
4 changed.

5 Q And so the Goodman case, as I
6 recall, it was a lung cancer -- excuse me.
7 The Goodman article was a lung cancer
8 article, right?

9 A That's correct.

10 Q So despite the change that you've
11 just described, you continue to hold the
12 opinion that there is a statistically
13 significant increased risk demonstrated by
14 the Goodman article?

15 A Yes.

16 Q If you look at paragraph 32 of your
17 report --

18 A Okay.

19 Q -- there's a reference discussing
20 the Hidajat study, and the statement is
21 "Exposure in the Hidajat, et al., study is
22 via inhalation rather than ingestion, but
23 Dr. Panigrahy has told me that NDMA and NDEA
24 are similarly carcinogenic via either route
25 (except that my calculations are conservative

1 because Dr. Panigrahy explained that some
2 amount of inhaled NDMA is exhaled)."

3 Did I read that correctly?

4 A You did.

5 Q Did you have any direct
6 conversations with Dr. Panigrahy?

7 A I did.

8 Q When did that occur?

9 A I don't know. Sometime in the last
10 few months.

11 Q Was it as you were preparing your
12 report?

13 A Sure.

14 Q Do you know Dr. Panigrahy?

15 A I've never met him face to face. I
16 may have interacted with him once before.

17 Q Do you recall in what context that
18 was?

19 A Zostavax. I'm not entirely certain
20 either. I think I did.

21 Q And in Zostavax, were you both
22 serving as experts for the plaintiff, to your
23 recollection?

24 A Yes, to my recollection.

25 Q How many discussions did you have

1 with Dr. Panigrahy regarding valsartan?

2 A Just one.

3 Q It was by telephone?

4 A Yes.

5 Q How long was the call?

6 A I don't know.

7 Q Have you reviewed his report?

8 A No.

9 Q Did you call him or did he call
10 you, or something else?

11 A Something else. Something else. I
12 can't remember. I think the attorneys --

13 Q That was my next question.

14 To your recollection, the
15 attorneys were also on that call?

16 A Yes.

17 Q What was the purpose of that call?

18 A To address this question.

19 Q And was that your question as to
20 whether or not inhalation and ingestion were
21 similarly carcinogenic?

22 A Yes.

23 Q And so you had a question regarding
24 whether you could draw conclusions about
25 ingestion of nitrosamines from a study that

1 focused on inhalation.

2 Is that fair?

3 A Yeah, that's -- that's basically
4 what I was asked about.

5 Q Why did you want to talk to
6 Dr. Panigrahy about that?

7 A Because it's outside my area of
8 expertise.

9 Q Did you do any independent research
10 on that question?

11 A No.

12 Q And by that, did you do any
13 literature research on that issue?

14 A Not that I can recall.

15 Q Do you remember Dr. Panigrahy's
16 response to that question?

17 A It's what's reflected in the
18 paragraph, in paragraph 32.

19 Q Did he say anything more than that?

20 A Not that I can recall.

21 Q Okay.

22 So then you took his response
23 at face value and used it as an assumption in
24 your report.

25 Is that fair?

1 A Yeah, that's fair enough.

2 Q Okay.

3 Do you want to take a break?
4 We've been going for a little while now.
5 Let's do that, give everybody and the court
6 reporter a break. Why don't we just come
7 back in about ten minutes. Sound good?

8 A Okay.

9 THE VIDEOGRAPHER: Okay. The
10 time is 10:49. We're off the record.

11 (Recess.)

12 THE VIDEOGRAPHER: The time is
13 11:06. We're back on the record.

14 BY MS. LOCKARD:

15 Q Okay.

16 Dr. Madigan, so if you'll take
17 a look at page 7 of your report, just a
18 couple of more questions about your change
19 with respect to the Goodman study.

20 And so if I direct you back to
21 the table. Given that you've adjusted the
22 16,363 down to 2,338, wouldn't that then
23 impact the P for trend column as well?

24 A No, it's nothing to do with that.

25 Q So it doesn't impact the last

1 column?

2 A No, that comes directly from the
3 Goodman paper.

4 Q And the effect size stays the same?

5 A Right. I calculated this lifetime
6 cumulative exposure, and that's not from the
7 paper. That's my calculation. But I did it
8 using information that was in the paper where
9 I thought something was per day but in actual
10 fact it was per week.

11 Q So let me just ask you in terms of
12 all of these columns, is the only one that
13 you actually calculated is the LCE column?

14 MR. NIGH: Form objection.

15 A That's a complicated question.
16 Let's go column by column -- not every
17 column, but there's a column called base high
18 dose.

19 Q Mm-hmm.

20 A So generally, I simply took that
21 from the paper, but in a few cases, I
22 estimated it.

23 Q Why did you do that?

24 A Because I had to.

25 Q Okay.

1 Because there wasn't an
2 express number in the paper?

3 A Right.

4 The next column, approximate
5 average age, in some of the papers it gives
6 you the average age. In others I had to
7 estimate it from information in the paper,
8 which I'm happy to talk about.

9 And then the LCE column indeed
10 is, you know, calculated using information in
11 the paper about milligrams per day.

12 The effect size comes directly
13 from the paper. Whether it's statistically
14 significant comes directly from the paper.
15 And the P value for trend comes directly from
16 the paper.

17 Q So as you -- as you're looking at
18 this, can you tell us specifically out of the
19 base high dose column which of those you
20 estimated versus took directly from the
21 paper?

22 A So the -- do you see -- let's look
23 at -- let's look at the last one, Zhu.
24 Right? So I have 1.24, and then I have that
25 symbol. So that refers to a footnote at the

1 bottom of the table. So it's -- for any
2 study where I have that symbol, so it's Zhu,
3 it's Keszei and it's Pobel.

4 So in those cases, I estimated
5 the -- the dose at the bottom of the highest
6 quartile.

7 And the method I used for that
8 is in Appendix A. I provide the R code in
9 Appendix A. Anyone can run this, see exactly
10 what I did.

11 Q What about the approximate average
12 age, which of the studies did you estimate
13 the age?

14 A We'd have to go through it one by
15 one. I can't tell you sitting here.

16 Q You'd have to look at the paper
17 again?

18 A Yeah.

19 Q Did you speak with any other
20 persons other than Dr. Panigrahy and
21 plaintiffs' counsel in preparing your report?

22 A No.

23 Q Am I pronouncing his name
24 correctly, Dr. Panigrahy? Do you know?

25 A I don't actually know.

1 MR. NIGH: So is the question
2 to him or is it --

3 MS. LOCKARD: I don't know --

4 MR. NIGH: -- plaintiffs'
5 counsel?

6 MS. LOCKARD: -- I thought you
7 were looking at each other, so I thought
8 there was a comment.

9 Q All right.

10 You don't know how to
11 pronounce Dr. Panigrahy's name, though, do
12 you?

13 A I'm embarrassed to say I do not.

14 Q All right.

15 Was there any information
16 provided to you by plaintiffs' attorney from
17 other experts that you relied upon in forming
18 your opinions in this case, other than what
19 we've already talked about?

20 A No.

21 Q And you did not speak with any
22 colleagues at the university about your
23 opinions in this case, did you?

24 A I did not.

25 Q Do you typically speak with any of

1 your colleagues or run ideas by them,
2 brainstorm, anything like that, about your
3 expert witness work?

4 A Typically, no.

5 Q And you didn't -- did not in this
6 case, right?

7 A Correct.

8 Q Okay.

9 Other than what's stated in
10 your report, did you make any other
11 assumptions about any facts or figures in
12 rendering your opinions in the case?

13 A No.

14 MR. NIGH: Form.

15 Q Did plaintiffs' counsel provide you
16 with any hypotheticals to be incorporated and
17 relied upon in generating your opinions in
18 the case?

19 MR. NIGH: Form objection.

20 A No.

21 Q Have you reviewed any additional
22 papers, studies or materials related to
23 valsartan since you completed your report?

24 A Not that I can recall.

25 Q Doctor, let me show you a document

1 that's been marked as Exhibit 7 to your
2 deposition. And this is the notice of
3 deposition in the case.

4 (Exhibit 7 marked for
5 identification.)

6 BY MS. LOCKARD:

7 Q Have you seen this previously?

8 A Yes.

9 Q Okay.

10 And did you -- let me -- let
11 me rephrase that.

12 That's actually -- Exhibit 7,
13 that's plaintiffs' objections and responses
14 to defendants' notice of deposition.

15 A Oh, all right.

16 Q So let me mark as Exhibit 8 --

17 (Counsel conferred.)

18 MS. LOCKARD: Let's strike the
19 exhibit numbering.

20 (Counsel conferred.)

21 MS. LOCKARD: So we're going
22 to reenter defendants' notice of videotaped
23 deposition as Defendants' 7, or Madigan 7.

24 BY MS. LOCKARD:

25 Q And so I'll ask you, Dr. Madigan,

1 have you seen this document before?

2 A I have, yes.

3 Q All right.

4 (Exhibit 8 marked for
5 identification.)

6 BY MS. LOCKARD:

7 Q And I'll give you now Exhibit 8,
8 which is Plaintiffs' Objections and Responses
9 to Defendants' Notice of Video Deposition of
10 David Madigan, PhD.

11 Have you seen that document
12 before?

13 A I do not believe so.

14 Q Were you engaged in responding to
15 our notice of videotaped deposition and the
16 request for documents that were attached to
17 it?

18 A Not that I recall.

19 MR. NIGH: Form objection.

20 Q Have you -- in connection with your
21 review of the notice, did you look at the
22 requests that are attached on page 6?

23 A Yes.

24 Q Did you make any effort to identify
25 the items that are requested?

1 A I went through this with the
2 attorneys, and it is my understanding that
3 anything that's responsive to this is
4 provided. [Unintelligible] I guess,
5 objections. I don't know.

6 Q All right.

7 And so we were provided a
8 stack of materials yesterday from plaintiffs'
9 counsel, and this is a printout of the stack
10 of materials that was produced as your file,
11 so I'm going to mark this as Exhibit 9.

12 (Exhibit 9 marked for
13 identification.)

14 MS. LOCKARD: Only have one
15 copy of this. And for the record, we do not
16 have an electronic copy of this, but we will
17 get it to the court reporter.

18 BY MS. LOCKARD:

19 Q What I'd like for you to do -- and
20 keep these materials in front of you, sir, if
21 you would, and just take a look at this, and
22 tell me, is this, to the best of your
23 knowledge, your complete file in this case?

24 A Can I write on this? Would that be
25 a problem?

1 Q Let me give you --

2 A Never mind. I have my own copy.

3 Maybe we can short-circuit
4 this. I'm assuming that everything that is
5 referenced in my report is here. I've --
6 certainly the studies that are in Table 1,
7 etc., I'm assuming they're all in here, but
8 if you want me to check one by one, it's
9 going to take me a little while.

10 Q I don't need you to check
11 everything that's in your actual report, and
12 we've confirmed that those items were in the
13 production, but there were a number of other
14 items that are in there that were not cited
15 in your report.

16 A I see. Okay.

17 Q Okay.

18 A So now I'm lost. So what's the
19 question?

20 Q The question is, is this -- what
21 was produced to us yesterday and is in front
22 of you as Exhibit 9, do you identify this as
23 your file in the case?

24 MR. NIGH: Form objection.

25 A Give me a minute.

1 MR. NIGH: And for the record,
2 this is Daniel Nigh, I'll represent that
3 these materials were produced electronically
4 from plaintiffs to defendants.

5 The way I see that statement,
6 Victoria, it sounded as if you said you don't
7 have an electronic copy, but we did send this
8 electronically. I think you meant that you
9 don't have electronic copies sitting here in the
10 room today.

11 MS. LOCKARD: Correct.

12 Right.

13 And just for clarification, my
14 point is, I don't have an electronic version of
15 that complete file, if that's what it is, put
16 into the exhibit folder on the Zoom, but we have
17 been produced a copy of Exhibit 9 electronically
18 from plaintiffs' counsel. So we're in
19 agreement.

20 A Okay.

21 So I certainly recognize
22 everything that's here. I believe this is
23 the totality of what you're calling my file,
24 yeah.

25 Q So as you sit here today, does

1 anything else come to mind that seems to be
2 missing?

3 A No, with the proviso I didn't
4 actually -- I didn't check if every single
5 study in Table 1 is here. It seems like they
6 were all here. But nothing else.

7 Q All right.

8 If you will turn to the
9 Exhibit 7 which is in evidence --

10 A Put this one aside?

11 Q Yes. Put this to one side for now.

12 All right. So the first
13 request was a copy of your current and
14 up-to-date CV. I know you produced a copy of
15 your CV with your report.

16 Do you have anything that's
17 more current and up-to-date?

18 A No.

19 MS. LOCKARD: All right.

20 So we'll mark as Exhibit 10 a
21 copy of the CV that was produced with your
22 report.

23 A It's already here.

24 MS. LOCKARD: Exhibit 10 is
25 your standalone CV.

1 A Okay.

2 (Exhibit 10 marked for

3 identification.)

4 BY MS. LOCKARD:

5 Q It's dated June 1, 2021, correct?

6 A Yes.

7 Q The second -- and we'll come back
8 to this a little bit later today, but the
9 second request in the notice of deposition
10 was to produce a list of all articles,
11 abstracts, studies, reports, seminar
12 materials, presentations, publications and so
13 on, from -- authored by you from 2011 to the
14 present.

15 Are all such materials listed
16 on your CV?

17 A Yes.

18 Q The third request -- well, let me
19 ask you this.

20 On your CV, are there any
21 papers, books or articles or presentations
22 that relate to nitrosamines?

23 A I don't believe so.

24 Q Have you written or presented on
25 the nitrosamines or valsartan issues since

1 you were retained in the case?

2 A Written -- other than what is here,
3 no.

4 Q Other than your report, have you
5 written anything for publication?

6 A No.

7 Q Do you intend to turn any of your
8 work in this case into a publication,
9 peer-reviewed or otherwise?

10 A That's not something I've thought
11 about.

12 Q Right.

13 Request No. 3 were documents,
14 presentations, speeches, papers that relate
15 to these issues in the case.

16 Assuming that you have not
17 spoken on these issues in the case, you
18 wouldn't have anything to produce.

19 Is that correct?

20 A I believe that's correct. The --
21 one of the caveats here was drug safety and
22 cancer risk, and I did search. I don't think
23 I have anything in that area.

24 I have a lot of publications
25 related to drug safety, but I don't think

1 anything specifically, you know, focused on a
2 drug safety issue which is -- that is cancer.

3 Q So just to clarify for the record,
4 you don't believe you have written or spoken
5 on drug safety with respect to cancer?

6 MR. NIGH: Form objection.

7 A Specifically. So, like, I have
8 many papers where they're methods papers
9 where I apply methods in lots of different
10 contexts. Is it possible that one of those
11 was cancer somewhere along the way? Yes,
12 it's possible, but I couldn't identify any.

13 Q But you don't have any papers,
14 publications or materials listed on your CV
15 that attempt to identify or assess the risk
16 of cancer.

17 Is that right?

18 A As a drug safety issue.

19 Q As a drug safety issue.

20 A Right, I do not. I don't believe I
21 do.

22 Q All right.

23 The list of cases which is
24 requested as No. 5, you provided that.

25 No. 6, we requested your

1 complete and entire file. You've now
2 identified that as what was produced
3 yesterday in Exhibit 9, correct?

4 A Yes.

5 Q I assume you didn't have any
6 communications with FDA, EPA or other federal
7 regulatory bodies about this case.

8 Is that right?

9 A That's correct.

10 Q And you have not reviewed any
11 deposition transcripts.

12 A No.

13 Q Have you asked for any deposition
14 transcripts?

15 A No.

16 Q And you have not made any notes or
17 calculations or memos yourself other than
18 what may be found within your report.

19 Is that correct?

20 A That's correct.

21 Q And you had discussed earlier that
22 you did do a search with respect to the Song
23 paper in looking for additional articles.

24 Are those -- were those
25 articles downloaded, saved by you and

1 included in your file?

2 A So the articles weren't, but the
3 search results I stored in an EndNote file
4 which should have been part of -- produced.

5 Q Can you confirm for us that it is
6 in fact in this file?

7 A I didn't see it.

8 Q You did not see it?

9 A Yeah. But I don't know how you
10 would you print it, though. It's proprietary
11 file for the -- you need the EndNote software
12 to open it.

13 Q All right.

14 But it's not in the file that
15 you produced yesterday?

16 A Can I look a little bit more?

17 Q Yes.

18 (The deponent read the
19 document.)

20 MS. LOCKARD: Do you know if
21 it's in there?

22 (Pause.)

23 A Yeah, it's not in this set of
24 printouts, in these hard copies.

25 Q All right.

1 If you wanted to produce the
2 information in the EndNote file, how would
3 you go about doing that?

4 A My laptop.

5 Q Is it -- so it's not something you
6 can convert into a document that can be
7 printed?

8 A I can print it. You know, I -- you
9 open it up in EndNote, you can print it.

10 Q Okay.

11 So you did not produce that to
12 your counsel, then?

13 A I did.

14 MS. LOCKARD: So we'll request
15 that that be produced and provided.

16 Q All right.

17 You haven't had any interviews
18 with anyone or taken any statements in
19 connection with this case, have you?

20 A I have not.

21 Q Have you had any other
22 communications with anyone else other than
23 Dr. Panigrahy and plaintiffs' counsel with
24 respect to valsartan?

25 A I have not.

1 Q Okay.

2 And Request No. 8 is for -- to
3 the extent you rely on for your opinions in
4 the case on specific patient experience,
5 produce all records pertaining to such.

6 Now, Mr. Nigh's response and
7 objection stated that you are not relying on
8 any specific patient experience.

9 Is that correct?

10 A Yes.

11 Q And we've asked for all invoice,
12 billing, billing records, time records. And
13 you've testified that you've provided us your
14 complete set of billing records and invoices
15 for this case, correct?

16 A Yes.

17 Q You've testified there are no
18 consulting contracts or retention letters,
19 correct?

20 A Correct.

21 Q And then No. 11, any other
22 information, documents, studies, texts,
23 treatises, objects or anything else that you
24 will use at trial.

25 Aside from what you produced

1 in your file, do you have any plans to use
2 any additional information, models, diagrams,
3 anything of that sort as you sit here today?

4 A Not as I sit here today, but I
5 would assume that if I was -- you know, I
6 might want to use slides if I was testifying.

7 Q And those have not been created
8 yet?

9 A Correct.

10 Q Okay.

11 And No. 11 is all other
12 documents reviewed by you in preparation for
13 the deposition other than communications with
14 counsel.

15 So in the past -- yesterday or
16 the weeks leading up to your deposition, did
17 you look at any additional documents outside
18 of what's in your file?

19 A I don't believe so.

20 Q All right.

21 You haven't reviewed anything
22 on the FDA website related to nitrosamines
23 other than what's cited in your report,
24 correct?

25 A Not that I can recall.

1 Q Did anybody assist you in drafting
2 your report?

3 A No.

4 Q Was it prepared by you and signed
5 by you?

6 A Yes.

7 Q Is that your signature on the front
8 page?

9 A Yes.

10 Q All right.

11 So let's take a look at the
12 report. If you want to turn to page 1.

13 And you understand when
14 preparing an expert report under the federal
15 rules for litigation like this, its purpose
16 is to identify all the opinions which you
17 intend to offer in the case and any bases
18 therefore, correct?

19 MR. NIGH: Form objection.

20 A I'm not familiar with the federal
21 rules, but yes, that is my understanding of
22 what's -- what the intent is here.

23 Q Okay.

24 And all of your opinions you
25 intend to offer in the case are contained

1 within that -- the four corners of that
2 report, correct?

3 MR. NIGH: Form objection.

4 A I believe that's the case. Yes,
5 that's the intention.

6 Q And all of the bases for each of
7 these opinions are contained within that
8 report.

9 Is that also correct?

10 MR. NIGH: Form objection.

11 A That's the intention.

12 Q Did you proofread your report
13 before you submitted it?

14 A Sure, yes.

15 Q Did you check your report to make
16 sure all citations were accurate before
17 submitting it?

18 A I did.

19 Q And did you check your report to
20 make sure that the proposition for which you
21 provided a citation is actually what is
22 stated in the reference material?

23 A Sorry, try that again? The
24 proposition?

25 What I was asked to do is in

1 the report. Is that what you mean?

2 Q Did you check to make sure all the
3 citations listed in your report, in your
4 footnotes, support the proposition for which
5 you've offered it?

6 A Yes, sure.

7 Q And you know it would be important
8 to proofread and check your citations before
9 submitting a report such as this in
10 litigation in federal court, right? That
11 would be important to do, don't you agree?

12 A Sure.

13 Q And as part of that, it's important
14 for the litigants, but it's also because your
15 professional reputation is on the line and
16 you want to make sure that your opinion is
17 reliable and accurate.

18 Is that true?

19 MR. NIGH: Form objection.

20 A There's a lot of vagueness in
21 there. My professional reputation is on the
22 line. I'm not entirely sure what you mean by
23 that, but sure, I intend this to be correct.
24 I want this to be correct.

25 Q All right.

1 You said in your report and in
2 the deposition that you were asked to perform
3 a statistical analysis to evaluate the
4 strength of association, dose response and
5 increased risk of the cancers reported in
6 certain dietary and occupational studies
7 which specifically examined exposure to NDMA
8 and/or NDEA, correct?

9 A Yes.

10 Q What do you mean by -- when you
11 describe a statistical analysis, what do you
12 mean by that for purposes of the jury's
13 understanding?

14 A So in this case, I mean statistical
15 interpretation of these studies. So I looked
16 at the information in the study about
17 strength of association, and about dose
18 response, and I report that in my -- extract
19 that from these studies and computed the
20 exposure and report that here.

21 Q What is the definition, if there is
22 one, of strength of association?

23 A So it refers to the association
24 between an exposure and an outcome. So to
25 what extent does -- you know, is being

1 exposed to something -- to what extent is it
2 associated with a particular outcome. Does
3 it increase the risk of the outcome or
4 decrease the risk of the outcome.

5 Q So would you agree it's the degree
6 of relationship between two or more
7 variables?

8 A Yeah, that's a broader definition.
9 I was being more specific to exposures and
10 outcomes.

11 But, yeah, sure, yours is --
12 yours is good, too.

13 Q Okay.

14 And the exposure and outcome
15 that you were assessing in this case would be
16 the exposure to nitrosamines and the outcome
17 of cancer, correct?

18 MR. NIGH: Form objection.

19 A Yeah, that's the nature of what I
20 was -- I was doing here.

21 Q Are there any other variables that
22 you considered in your analysis other than
23 what's documented in the literature you
24 reviewed?

25 MR. NIGH: Form objection.

1 A Other than what's in the literature
2 that I reviewed. No, I don't think so. I
3 don't really understand the question,
4 actually.

5 Q What -- can you define what you
6 meant by dose response for the jury's
7 benefit?

8 A So that's an examination of whether
9 the association strengthens or weakens as you
10 increase the dose.

11 Q In analyzing the dose response in
12 this case, did you presume a linear dose
13 response relationship between nitrosamines
14 and cancer?

15 A I didn't presume any association.
16 I looked at the papers to see what they
17 reported, the studies.

18 Q You looked at the papers to see
19 what was reported.

20 A Yeah.

21 Q So in the papers that you reviewed,
22 you did not undertake any independent
23 analysis to verify the dose response that was
24 reported?

25 A Independent analysis. If you mean

1 did I conduct my own analysis of their data,
2 no, I did not, because I don't have the data.
3 For these -- each of these studies, I don't
4 have access to the data that the study
5 authors have access to.

6 Q The data that is available for each
7 of the studies would not be publicly
8 available, correct?

9 MR. NIGH: Objection.

10 A Generally not. You wouldn't expect
11 it to be.

12 Q In order to get the data, you would
13 have to approach each of the authors
14 individually and have them send it to you,
15 correct?

16 A In order to get the data, yes, you
17 probably -- you might or might not have any
18 success, but that's how you would go about
19 it.

20 Q Did you make any effort to reach
21 out to any of the authors of the papers you
22 reviewed to ask for the data they relied
23 upon?

24 A I did not.

25 Q In each of the papers you reviewed,

1 did you make any assessment to verify if the
2 dose response described in the paper was in
3 fact linear?

4 A So we'd have to go -- sorry, can
5 you ask the question again?

6 Q So my question is, did you look at
7 each of the papers and do an assessment to
8 determine if the dose response was in fact
9 linear?

10 A So I don't have access to the data,
11 the raw data, so I'm relying on the analysis
12 that the authors did. That's what I'm
13 looking at.

14 So in, you know, in most
15 cases, they tested for a linear trend, and
16 that's what I report here in the table. We'd
17 have to go through it one by one. It wasn't
18 necessarily linear in every case.

19 Q Okay.

20 So you'll be able to tell us,
21 though, of those which are reported -- which
22 reported a linear trend and which didn't? Is
23 that -- is that -- you're saying from the
24 table? What do you need to look at in order
25 to tell us whether or not each report -- the

1 paper itself?

2 A The paper itself.

3 Q Okay.

4 That's not noted in your
5 report, in other words, correct?

6 MR. NIGH: Object to form.

7 A What's not noted? I'm not with
8 you.

9 Q Whether or not the authors reported
10 a linear dose response relationship in their
11 paper.

12 In other words, you didn't
13 notate in your report whether or not each of
14 those authors noted a linear dose response?

15 A I reported the p-value for the
16 trend, and we'd need to look at the
17 individual papers to see whether -- I think
18 they're actually linear in every case, but
19 we'd have to look at the individual papers to
20 check that.

21 Q Can you recall -- without looking
22 at the individual papers, can you recall any
23 of them that does not report a linear trend?

24 A I'm not -- I can't answer that
25 question. I need to look at the papers. I

1 know the Song meta-analysis specifically
2 reports on nonlinear -- they did a test for
3 nonlinear trend.

4 The individual papers, I don't
5 think so, but we'd have to go through them
6 one by one.

7 Q All right.

8 Did your conclusions in your
9 report -- well, strike that. We'll pull up
10 some of the papers in a few minutes.

11 All right.

12 Define what you mean by
13 "increased risk of cancer."

14 A An association -- a measure of
15 association that -- whether it's a relative
16 risk or an odds ratio or a hazard ratio
17 that's bigger than one. In this context
18 that's what I mean.

19 Q Okay.

20 What do you understand to be
21 meant by hazard ratio?

22 A So it's a measure of effect size
23 that's related to time to event.

24 Q So in evaluating a hazard ratio, it
25 takes into account the variable of time.

1 Is that fair?

2 A Yes. That's not a unique
3 characteristic of the hazard ratio, but that
4 is -- the way you asked is fine. That is a
5 characteristic of a hazard ratio.

6 Q So if we start on page 1 of your
7 report, it looks like there's a background
8 section.

9 The first page and a half
10 actually appears to be background section,
11 correct?

12 A That is correct.

13 Q Is this a template that you start
14 with, background, introduction, and so forth
15 for each of your reports you do in
16 litigation?

17 A I wouldn't call it a template. I
18 copy it from another report. I don't write
19 it from scratch each time.

20 Q So is the -- you used essentially
21 the same background, first page and a half,
22 in every report?

23 A Pretty much. I might make tweaks.
24 I don't -- generally, yes.

25 Q And the first page and a half is

1 your background. It doesn't offer any
2 opinions about the valsartan case, right?

3 A That is correct.

4 Q All right.

5 So if we look at the
6 Introduction section, there are two
7 paragraphs, 6 and 7.

8 Paragraph 6 appears to be
9 factual assertions that provide context to
10 your report.

11 Is that a fair characteristic?

12 A Sure.

13 Q There are no opinions in
14 paragraph 6 that I can see.

15 Is that right?

16 A There are no opinions that are
17 unique, that are my original opinions. I'm
18 citing facts.

19 Q Okay.

20 So paragraph 6 contains none
21 of your original opinions.

22 Is that fair?

23 A Yeah, I think that's reasonable.

24 Q Okay.

25 And so each of the factual

1 assertions in paragraph 6 is then footnoted,
2 and so you're relying on the accuracy of
3 what's reported in the footnote.

4 Is that correct?

5 A I'm relying on the accuracy of
6 what's in the footnote. I mean, I'm
7 extracting things from those sources.

8 MR. NIGH: Form objection.

9 Q Okay.

10 And you're assuming the data
11 that you've cited here and supported by the
12 footnote to be correct, or else you wouldn't
13 have cited it, right?

14 A Sure.

15 MR. NIGH: Form objection.

16 Q And so, for example, where it says
17 in paragraph 6, US Department of Health and
18 Human Services -- let me read it correctly.

19 "According to the US
20 Department of Health and Human Services,
21 N-nitrosodimethylamine (NDMA) is reasonably
22 anticipated to be a human carcinogen."

23 You're not offering an opinion
24 about whether NDMA is a human carcinogen or
25 reasonably expected to be so, correct?

1 MR. NIGH: Form objection.

2 A I suppose I am not. Why I'm
3 hesitating here is I -- you know, the
4 analysis I did in the report here is germane
5 to that question. But other than that, I
6 have no -- you know, I don't have an
7 independent opinion. Am I --

8 Q Well -- and then there's a quote
9 from IARC essentially saying that NDMA is
10 probably carcinogenic to humans. And you're
11 just quoting that from the IARC?

12 A Correct.

13 Q Okay.

14 There's the statement the
15 USFDA has indicated that levels of NDMA up to
16 0.096 micrograms per day and levels of NDEA
17 up to 0.0265 micrograms per day are safe.

18 Again, not your opinion.
19 You're relying on the information provided by
20 the FDA, correct?

21 A I'm just reporting as a fact that
22 that's what the FDA indicates.

23 Q And then you note: "More recently
24 Johnson, et al., have suggested that NDMA
25 levels as high as 6.2 micrograms per day and

1 NDEA levels as high as 2.2 micrograms per day
2 could be safe levels of NDMA" --

3 A That's the wrong one.

4 Q I'm sorry. It was. Let me restate
5 that question.

6 You go on to state: "More
7 recently Johnson, et al., have suggested that
8 NDMA levels as high as 6.2 micrograms per day
9 and NDEA levels as high as 2.2 micrograms per
10 day could be safe."

11 Correct?

12 A Correct. I've lost track of the
13 question.

14 So the -- you know, I'm just
15 reporting that's what these people said.

16 Q Do you know Dr. Johnson?

17 A No.

18 Q Did you read his papers that you
19 cited?

20 A Yes, I believe so, I did.

21 Q Okay.

22 And did you understand it's
23 one of the first peer-reviewed papers to be
24 published on nitrosamine exposure limits?

25 MR. NIGH: Form objection.

1 A Do I understand it? No, I didn't.

2 I don't know anything about that.

3 Q And in pharmaceuticals.

4 MR. NIGH: Form objection.

5 A Sorry, what's the question?

6 Q It's not a question. I just wanted
7 to correct my statement.

8 A Okay.

9 Q And I'll restate it for clarity.

10 But when you reviewed the
11 Johnson paper, did you understand that it was
12 one of the first papers -- peer-reviewed
13 papers to be published on nitrosamine
14 exposure limits in pharmaceuticals?

15 MR. NIGH: Form objection.

16 A So the question is did I understand
17 that? No.

18 Q Do you know anything about
19 Dr. Johnson or his professional reputation?

20 A No.

21 Q All right. So I'll just for the
22 record mark the Johnson paper that you cited
23 to in your report as Exhibit 11.

24 (Exhibit 11 marked for
25 identification.)

1 BY MS. LOCKARD:

2 Q Did you read this paper in its
3 entirety or did you, you know, more or less
4 skim it?

5 A I think I read it. I don't recall
6 exactly.

7 Q As you sit here today, I assume you
8 don't have any basis to quarrel with his
9 conclusions?

10 MR. NIGH: Form objection.

11 A It's outside my area of expertise.

12 Q So you would not -- you would not
13 endeavor to criticize Dr. Johnson's
14 conclusions or his paper because it's outside
15 of your expertise, correct?

16 MR. NIGH: Form objection.

17 A I don't think so. I mean, I'd have
18 to look, refresh my memory here to see are
19 there statistical or epidemiological issues
20 that I could opine on. But, you know, in
21 general, this -- the topic here is outside
22 the scope of my expertise.

23 Q And you -- I presume you found it
24 to be a reliable and authoritative paper or
25 you wouldn't have cited it in your report.

1 Is that correct?

2 MR. NIGH: Objection.

3 A I wouldn't go so far. I was just
4 noting that, you know, the FDA has said
5 certain levels are safe. I was just noting
6 that in the literature there are some people
7 saying there are safe levels that are higher.
8 That's all.

9 Q And his conclusion was based on a
10 permissible daily exposure analysis, and his
11 conclusion was that the PDE provides a more
12 robust assessment of exposure limits as
13 compared with the simple linear
14 extrapolations that underlie the acceptable
15 daily limits reported by FDA?

16 MR. NIGH: Objection to form.

17 A I don't recall. If you want to
18 point me to something in the paper, I can
19 refresh my memory, but I don't recall.

20 MR. NIGH: Do I get a copy of
21 this?

22 MS. LOCKARD: Yes, sir, I do
23 have a copy for you. Thank you.

24 Q So, if you will, Dr. Madigan, if
25 you will turn to page 3 of the report.

1 A No page numbers.

2 Q Well, count to the fourth page,
3 there's an abstract.

4 Are you with me?

5 A This is a preprint, by the way, not
6 the published version. It probably doesn't
7 matter, but I'm just noting.

8 Q Well, the last sentence of the
9 abstract says: "These PDE calculations using
10 a benchmark approach provide a more robust
11 assessment of exposure limits compared with
12 simple linear extrapolations and can better
13 inform risk to patients exposed to the
14 contaminated sartans."

15 So did I read that correctly?

16 A You did.

17 MR. NIGH: Object to form.

18 Q So you don't intend to offer any
19 opinions or criticisms about that conclusion
20 by Dr. Johnson, correct?

21 A I do not.

22 MR. NIGH: Object to form.

23 Q Did you find this paper yourself or
24 did counsel send it to you?

25 A I don't recall.

1 Q You're not a genetic toxicologist,
2 I presume?

3 A I am not.

4 Q Is toxicology outside of your area
5 of expertise?

6 MR. NIGH: Object to form.

7 A Generally, yes.

8 Q All right. You can put that aside.

9 Okay. So moving along in your
10 report, if you will, the next sentence in
11 your introduction says: "Levels of NDMA in
12 contaminated valsartan tablets range from
13 below the limit of detection to
14 20.19 micrograms, while levels of NDEA in
15 contaminated valsartan tablets range from
16 below the limit of detection to
17 1.31 micrograms."

18 Did I read that correctly?

19 A Yeah, you did.

20 Q All right.

21 So you then cited the Snodin
22 article entitled "Short commentary on NDMA
23 contamination of valsartan products," and you
24 cited the FDA website, correct?

25 A Right.

1 Q All right.

2 Let's mark as an exhibit to
3 your deposition the FDA website. What is
4 this? Exhibit 12.

5 (Exhibit 12 marked for
6 identification.)

7 BY MS. LOCKARD:

8 Q So I'm showing you what's entitled
9 the "Laboratory analysis of valsartan
10 products." And if you turn to the second
11 page, there's a table there.

12 Is this what you intended to
13 cite to in your report?

14 A Yes.

15 Q All right.

16 Now, I presume you haven't
17 taken any efforts to independently verify the
18 data that's listed in terms of the levels
19 found in this chart, correct?

20 A Correct.

21 Q Now, do you have an understanding
22 as to whether the levels noted are for
23 finished dose versus API product?

24 A It's my understanding based on
25 this -- at face value, and they're referring

1 to the amount of NDMA in tablets.

2 Q So then it's your understanding of
3 this chart that all of these numbers are
4 finished-dose testing levels?

5 A The phrase "finished-dose testing
6 levels," I don't know what you mean by that.

7 It's my understanding that
8 they tested tablets and measured the amount
9 of NDMA in tablets.

10 Q Are you aware of any testing that
11 was done on API that was used to manufacture
12 the tablets?

13 A I am.

14 Q Have you seen any test results for
15 the API?

16 A There's two references in my report
17 that contain testing results for -- at least
18 one of them does, testing results for APIs.
19 I think both do.

20 Q Are you referring to the company
21 documents?

22 A Right.

23 Q All right.

24 And so just for clarity,
25 you're referring to what's listed under

1 footnote 6 and footnote 7 in your report?

2 A Right.

3 Q And so it's your position that
4 footnote 6 and footnote 7 included testing of
5 API.

6 Is that right?

7 A That's my memory, yeah. We
8 should -- we can look at it.

9 Q Right.

10 Now, so, you understand the
11 difference between API and finished-dose
12 tablets, correct?

13 A The finished -- you're using the
14 phrase "finished-dose tablets." I'm not
15 familiar -- I could guess what you mean by
16 that, but it's not a term that's familiar to
17 me.

18 Q Okay.

19 So "finished dose," that
20 phrase is not familiar to you?

21 A That's what I just said.

22 Q Okay. All right.

23 So if we refer to what the
24 patient actually ingested, can we agree to
25 call it tablets?

1 A Sure.

2 Q Okay.

3 All right. So for clarity,
4 the FDA chart, your understanding is that's
5 testing of all tablets. What's noted in 6
6 and 7, footnotes, are testing of API?

7 A No, no. That's not what you asked
8 me.

9 So you asked me was there
10 testing of APIs in these documents. Answer,
11 yes.

12 Are there other things in
13 these documents? Yes, there are.

14 Q Okay. That's fair. That's fair.
15 All right.

16 So, now, I see the numbers
17 that you had listed, the 20.19, is that
18 you're taking from the FDA chart where
19 there's Princeton Pharmaceutical and the
20 highest number in the column is 20.19?

21 A Yes.

22 Q And likewise, the highest number
23 that you provide in your report is the 1.31,
24 which you found --

25 A The last one.

1 Q -- in the last one on the next page
2 for Torrent, correct?

3 A Yes.

4 Q Now, you also cited the Snodin
5 article. We'll mark that as Exhibit 13.

6 (Exhibit 13 marked for
7 identification.)

8 BY MS. LOCKARD:

9 Q Was the Snodin article provided to
10 you by counsel or did you locate that
11 yourself?

12 A Don't recall.

13 MS. LOCKARD: Do you want a
14 copy of this, Daniel?

15 MR. NIGH: Yes.

16 Q And again, you haven't done any
17 assessment as to the reliability of the
18 Snodin paper itself.

19 Is that fair?

20 A An assessment of the reliability of
21 the paper. So I only -- I cited to it as
22 another source for the -- the NDMA levels,
23 but they're directly taking that from the
24 same website that we were just looking at.

25 Q Okay.

1 And you're citing this paper
2 for both the NDMA and NDEA levels?

3 A Oh, that I don't remember.

4 Q Okay.

5 A I just don't recall.

6 Q I'll represent to you that I could
7 not find in the Snodin paper the NDEA level
8 of 1.31 for which you listed Snodin as a
9 reference.

10 MR. NIGH: Object to form.

11 A That's overstating it. I listed
12 Snodin as a reference to a compound sentence
13 that had two different things in it, so I did
14 not -- that, to me, does not imply that the
15 citation pertains to every last thing in the
16 sentence.

17 Q So what are you attributing to the
18 Snodin article in that sentence?

19 A I don't recall exactly. The -- the
20 20.19 is rounded to 20 in the -- in a table
21 in this paper. I just don't recall. If you
22 want, we can take the time and I can read it.
23 I just don't recall if the -- you're
24 representing it's not there. Maybe you're
25 right. I'd have to read it again to remember

1 whether the 1.31 is in there or not.

2 Q Okay.

3 Do you remember whether the
4 20.19 is in the Snodin paper?

5 A Couldn't tell you. I'd have to
6 read it. I see the 20, a rounded -- they're
7 not using -- they're rounding these to the
8 nearest integer in Table 1, but I'd need to
9 read the paper to recall whether 20.19 is in
10 there.

11 Q Did you look up any of the articles
12 that were cited in the Snodin paper yourself?

13 A I don't -- I looked at the FDA
14 article, the website. I don't recall.
15 Beyond that, I -- no memory.

16 Q Other than what's printed in the
17 Snodin article and the FDA website, along
18 with the footnote 6 and 7 for the ZHP and
19 Torrent documents, you have no knowledge or
20 information about the testing that was done
21 on any manufacturer's products, do you?

22 MR. NIGH: Form objection.

23 A I am not aware of any other
24 documents that -- I don't believe I've seen
25 any other documents that list NDMA levels

1 detected in -- in these products. I'm not
2 aware. I don't think there's anything else,
3 other than what you just talked about.

4 Q Okay.

5 And you don't have any
6 independent knowledge regarding the actual
7 test results of defendants' products, do you?

8 MR. NIGH: Form objection.

9 A Independent knowledge. Are you
10 asking the same question? Do I know
11 anything -- do I have any information outside
12 of what's cited here? Is that the same
13 question?

14 Q You haven't seen the raw testing
15 data, right?

16 A Raw testing data. I don't know
17 what that is.

18 MR. NIGH: Objection, form.

19 A The footnote 6 and 7 are pretty
20 darn raw, so I don't know what you mean.

21 Q So you haven't seen any other
22 testing data other than what you've cited in
23 your footnote 5, 6 and 7?

24 MR. NIGH: Object to form.

25 A That's what I said a few minutes

1 ago. Yeah, I believe that's right.

2 Q All right.

3 So let's take a look at the
4 document that you've cited as No. 6 on the
5 footnote. And this is -- I believe it's
6 marked as restricted confidential, so we'll
7 need to follow the protocol in the protective
8 order for this.

9 (Counsel conferred.)

10 MS. LOCKARD: Okay.

11 So I know counsel for ZHP is on.
12 If you have any objection to me introducing
13 this, let me know. We can have it redacted at
14 the end.

15 MS. HILL: I think we're fine
16 with just following the protocol and we can
17 redact it later.

18 (Exhibit 14 marked for
19 identification.)

20 BY MS. LOCKARD:

21 Q So handing you what's been marked
22 as Exhibit 14, Dr. Madigan. So if you could
23 take a look at that, does it appear to be the
24 same document that you reviewed --

25 MR. NIGH: Can I have a copy

1 of this one?

2 MS. LOCKARD: It's -- it's
3 right here. My arms are too short.

4 BY MS. LOCKARD:

5 Q Does it appear to be the document
6 you reviewed and cited as Exhibit 6?

7 MR. NIGH: Form objection.

8 A No.

9 MR. NIGH: Just state for the
10 record, it appears that the columns are
11 broken up into -- that is, you can't match
12 the columns on the document handed to me
13 to -- you can't see the complete columns on
14 this document. They're broken up.

15 MS. LOCKARD: I agree it is
16 difficult to read.

17 THE DEPONENT: There's a more
18 fundamental problem, I think, which is that
19 spreadsheet has two tabs. I think this is
20 only one of the tabs. This is a printout of
21 essentially half the -- half the document, I
22 think.

23 BY MS. LOCKARD:

24 Q Okay.

25 So I -- it was pulled by our

1 staff. It has -- in your -- in your
2 footnote, just for the record, it has
3 SOLCO000028261, and in -- on the front cover
4 of the document I just handed you, it has the
5 same Bates number.

6 But I understand what you're
7 saying is that you looked at a separate tab.

8 A Two tabs in the spreadsheet.

9 Q And what you're looking at here
10 is -- appears to be Tab 1?

11 A I don't know. I don't know. I --
12 it definitely appears to be -- I can't
13 remember what's in the stack, right? There
14 was a printout of -- related to this in the
15 stack.

16 Q I didn't see it in the stack, which
17 is why I started to ask you -- actually --

18 A It should be there. I think
19 that's --

20 Q Is this it?

21 A I don't know if it's any better.
22 Might have the same problem.

23 Q Okay.

24 Let's try this one. We'll
25 mark this as Exhibit 15. This is the table

1 that was contained within your file
2 materials, and it's set up in a landscape
3 version.

4 (Exhibit 15 marked for
5 identification.)

6 MR. NIGH: You don't have a
7 copy of this one for me?

8 MS. LOCKARD: I don't.

9 MR. NIGH: Okay.

10 (The deponent read the
11 document.)

12 A This appears to be complete.

13 Q Okay.

14 A I can't be certain, but it
15 appears -- I'm looking for the value that --
16 from which I derived the 60.2 that's in my
17 report, and it's here. I see it.

18 Q Okay.

19 If you'll take a -- take a
20 highlighter and just circle the number -- the
21 position where you derived that 60.2 number
22 for NDMA.

23 MR. NIGH: I need to take a
24 look at this one, see if this is --

25 THE DEPONENT: I'm not sure if

1 it's complete, but it has -- it does have the
2 one entry that I had used.

3 (Counsel read document.)

4 MR. NIGH: Yeah. And just for
5 the record, you can't tell by looking at this
6 printout if it's got every tab printed out
7 for this Socol number, but it refers to
8 the --

9 This is an Excel spreadsheet, so
10 that's my point behind this.

11 MS. LOCKARD: Okay.

12 And it's an Excel spreadsheet
13 that plaintiffs' counsel produced to defendants
14 from Dr. Madigan's file, so if it's not
15 complete, we received it in an incomplete
16 fashion.

17 MR. NIGH: No, I don't agree
18 with that representation. You -- I don't
19 know how your staff printed this. They would
20 have to go through each tab and print the
21 potential -- so it's hard to tell by looking
22 at this document versus comparing it to
23 native format whether or not it contains the
24 entire document and all the tabs.

25 BY MS. LOCKARD:

1 Q Well, you've identified for us,
2 Dr. Madigan, on this line here the row that
3 you believe supports the assertion that the
4 levels were as high as 60.2?

5 A Yes.

6 Q How did you reach the conclusion of
7 60.2 from the data that's here?

8 A So you multiply the parts per
9 million by, in this case it's .32, which is
10 the -- for a 320-milligram tablet, the
11 conversion is you multiply that by .32, and
12 that gives you the milligrams in a tablet.

13 Q And that's how you reached your
14 conclusion of the 60.2 high level?

15 A Yes.

16 Q All right.

17 So I'll mark as Exhibit 16
18 TORRENT-MDL2875-00133890 [sic] and ask you if
19 you can identify this as the document cited
20 in your paper as footnote 7.

21 (Exhibit 16 marked for
22 identification.)

23 MS. LOCKARD: This is also
24 noted as confidential, so if counsel for
25 Torrent is on the line, if you have any

1 objection to us introducing this or following
2 the protocol, please let me know.

3 BY MS. LOCKARD:

4 Q All right. So you can do the same
5 thing.

6 If you could take a look at
7 this and identify where in that document you
8 found evidence for the 5.4 NDEA.

9 A Can I highlight?

10 Q Yes.

11 A Let me just do a quick calculation
12 to make sure I've identified the right --
13 yes, that's correct.

14 Q Okay.

15 And for the record, you've
16 highlighted row 16 and 17 in the chart on
17 page 5 of 6, and the results of NDEA are
18 listed as 16.93.

19 Can you explain how you
20 derived the numbers in your report of
21 5.4 micrograms from that chart?

22 A So same thing, multiply it by .32.

23 Q Did you -- did you receive these
24 documents from counsel?

25 A Yes, yes.

1 Q These two?

2 It's not something you found
3 on your own, right?

4 A Right.

5 Q Did you ask counsel to provide you
6 with certain testing results?

7 A I don't recall exactly, but I said
8 I'd be interested to see anything that would
9 show the amount of NDMA in the -- in the
10 products.

11 Q And I think you said those were the
12 two company documents that you were provided
13 that had any testing results on them,
14 correct?

15 A Yes, that's correct.

16 Q All right.

17 Turning back to your report,
18 paragraph 7, and we discussed that the
19 studies referenced in paragraph 7, which you
20 refer to as certain dietary and occupational
21 studies, were studies that were relied on by
22 Dr. Etminan that you were asked to consult
23 on.

24 Is that correct?

25 A Yes.

1 Q Did you request dietary and
2 occupational studies or were they just
3 provided to you?

4 MR. NIGH: Form objection.

5 A I was asked to consider the studies
6 that, you know, emerged from Dr. Etminan's
7 search. They are dietary and occupational in
8 nature.

9 Q Did you at any time review any
10 pharmaceutical studies or published papers
11 regarding nitrosamine exposure?

12 MR. NIGH: Form objection.

13 A Pharmaceutical -- I don't
14 understand what you mean.

15 Q Any papers that looked at the issue
16 of cancer risk from exposure via
17 pharmaceutical ingestion. Did you look at
18 any such papers?

19 MR. NIGH: Form objection.

20 A So yeah, I have seen the Pottegard
21 paper.

22 Q And that was in the materials
23 provided, correct?

24 A Right.

25 Q Did you find the Pottegard paper

1 yourself?

2 A I don't recall it. Maybe I did it
3 early on. I don't remember.

4 Q Why did you look at the Pottegard
5 paper?

6 A Because it pertained broad strokes
7 to the topic I was studying here.

8 Q Were you asked to look at the
9 Pottegard paper by anyone?

10 A I don't recall. I don't think so.

11 Q Did you perform a statistical
12 analysis to evaluate the strength of the
13 association, dose response, and increased
14 risk of the cancer addressed in the Pottegard
15 paper?

16 A I -- not directly. There isn't --
17 it's not germane to those questions in
18 particular.

19 What I did do was -- you know,
20 it's an observational study. I reviewed --
21 which I have a lot of expertise in. I
22 reviewed it as a study, and I have opinions
23 about it. They weren't germane to the
24 questions I was being asked here.

25 Q What are your opinions about the

1 Pottegard study?

2 A So it compares -- it -- it
3 considers valsartan users and follows them
4 for some period of time, a relatively short
5 period of time in terms of a cancer study.

6 It divides people who are
7 exposed into contaminated valsartan and
8 uncontaminated valsartan. There are real
9 questions about -- about the -- the accuracy
10 of that -- of that discrimination. But leave
11 that aside for a second.

12 And then they looked forward
13 in terms -- so you've got two groups of
14 people, basically, you know, valsartan
15 uncontaminated and valsartan contaminated.
16 And then they looked to see, you know, how
17 many cancers occurred in these two groups.

18 There's a fundamental problem
19 with the paper, though, which is it considers
20 all users of valsartan, regardless of whether
21 they were new users at the time this -- the
22 study -- the study was begun, regardless of
23 whether they were new users or existing users
24 of valsartan.

25 And the state of the art in

1 epidemiology in recent years has moved very
2 much towards new user studies. So you
3 identify new users of Drug A and new users of
4 Drug B and study -- you know, study those
5 people.

6 I myself have published a
7 bunch of new-user studies in the last years.
8 And the -- the reason is, if you include in
9 the study people who are continuing users of
10 valsartan in addition to new users, the
11 people who are continuing users are
12 different. They're people for whom the drug
13 is tolerated. They're people for whom the
14 drug in this case probably works, is
15 effective with regard to their hypertension.

16 So it introduces all kinds of
17 potential confounding factors when you take
18 all comers.

19 So this was discussed,
20 actually, by -- I also have the reviews, the
21 peer reviews of the Pottegard paper. So what
22 I just said was part of one of the -- one of
23 the reviewers pointed this out.

24 In actual fact, in the paper
25 itself, it did do a sub-group analysis

1 confined to new users, and then for those
2 folks is the more -- is the cleaner kind of
3 higher-quality analysis.

4 When you restrict it to new
5 users of valsartan and compare contaminated
6 with uncontaminated, and the effect size, my
7 memory is it's 1.6, approximately, so 60
8 percent increased risk of cancer.

9 And the confidence interval
10 just misses statistical significance, it
11 begins at 0.99 is my memory. I don't know
12 what it goes up to. Something above .6.

13 So -- so that study, to me, is
14 actually -- says -- is very problematic with
15 regards to the risk associated with
16 contaminated valsartan.

17 Q Because of the failure to
18 distinguish the new users?

19 A Right. That's a -- if -- sort of
20 fundamental flaw in that paper. It's
21 particularly problematic here because the new
22 users were about twice as prevalent in the
23 contaminated group as in the uncontaminated
24 group. So it's not like the new users were
25 spread evenly between the two groups.

1 So they -- the authors
2 responded to the reviewers with a response
3 that frankly was nonsensical. It didn't
4 actually address the issue.

5 And the -- you know, I think
6 the editor of the paper just, you know, let
7 it through. In my opinion, he or she
8 shouldn't have done that.

9 Q Well, that was included in your
10 file, and the letter response itself, was
11 that provided to you by plaintiffs' counsel
12 or did you locate that yourself?

13 A That was provided by counsel. I
14 wouldn't have access to that.

15 It's in the stack.

16 MS. LOCKARD: I think I have
17 copies in here. We may have to take -- let's
18 just take a break so I can get organized.
19 It's also 12:20, so I don't know if you
20 intend to take any sort of lunch break.
21 We're going to need to take a break, I think,
22 for everybody on the call, the court
23 reporter.

24 Daniel, do you have any
25 preference in terms of timing?

1 THE DEPONENT: Short.

2 MR. NIGH: Short.

3 THE VIDEOGRAPHER: Okay, do
4 you want me to go off the record?

5 MS. LOCKARD: Yes, let's go
6 off the record.

7 THE VIDEOGRAPHER: Okay. The
8 time is 12:22. We're off the record.

9 (Lunch recess.)

10 THE VIDEOGRAPHER: The time is
11 1:14. We're back on the record.

12 MR. NIGH: Okay. I just want
13 to put on the record that Dr. Madigan has a
14 hard stop at 6:15 Eastern today. We started
15 this deposition at -- 9:00 was the notice of
16 deposition. We weren't able to start until
17 about 9:35.

18 Hopefully this doesn't become an
19 issue and we can take some quicker breaks, but
20 we did stress to try to get back in here at
21 12:50. Looks like we're going to start at about
22 1:15. Plaintiffs' counsel was ready at
23 with the witness.

24 Hopefully we won't have an issue
25 but at this point I think we only have about a

1 little over two and a half hours of record time,
2 and he's going to have to leave, he's got a hard
3 stop at 6:15.

4 THE DEPONENT: I have to be in
5 Brookline at 6:45, or I will be murdered.

6 MS. LOCKARD: Okay.

7 Well, we don't want that to
8 happen. I mean, we're going to take our
9 deposition time, and, you know, I don't think
10 we've been unreasonable on breaks. So I take
11 issue with the sense that we've been taking
12 extra-long breaks. I don't think that's
13 appropriate. But I think we should get back on
14 the record and see where we are. And we'll see
15 if it's an issue.

16 BY MS. LOCKARD:

17 Q All right, Dr. Madigan.

18 So we were going through your
19 report previously. Do you have that in front
20 of you?

21 A Yes.

22 Q All right.

23 A Sorry, I have the --

24 Q That's okay.

25 So on paragraph 7, so the last

1 statement that you have there: "These are
2 all observational studies and I have
3 discussed the strengths and limitations of
4 observational studies in several
5 publications."

6 Did I read that correctly?

7 A Yes.

8 Q And then you cite to one of your
9 own publications, which is cited at
10 footnote 8, A systemic [sic] statistical
11 approach to evaluating evidence from
12 observational studies.

13 And why did you pick that
14 article to site for that proposition?

15 A It expresses many of my opinions
16 about observational studies. I have many
17 papers that I could have cited to. But that
18 one is a fairly complete review at that time.

19 Q And throughout some of your papers
20 and even your testimony, you have offered a
21 number of criticisms and limitations of
22 observational studies, correct?

23 A Yes.

24 Q All right.

25 And one of the papers that you

1 have written in addition to the one that
2 you've cited is one called "Evaluating the
3 impact of database heterogeneity on
4 observational study results," accepted for
5 publication January 17, 2013. Correct?

6 A Yes.

7 (Exhibit 17 marked for
8 identification.)

9 BY MS. LOCKARD:

10 Q And this is --

11 MS. LOCKARD: Sorry, Daniel.

12 Q So this is one of your papers where
13 you include criticisms and limitations of
14 observational studies.

15 A Sure. Number?

16 Q Exhibit No. 16.

17 A No, 17.

18 Q 17, Exhibit 17.

19 All right. And in this paper,
20 you stated --

21 (Discussion off the record.)

22 MR. NIGH: The spreadsheet was
23 marked as two exhibits?

24 THE DEPONENT: The spreadsheet
25 was 15. Torrent is 16.

1 MS. LOCKARD: All right.

2 Let's go with 17. We'll figure it out.

3 BY MS. LOCKARD:

4 Q All right.

5 So in this study, Dr. Madigan,
6 I'm going to read in the executive summary at
7 the beginning. There's a statement, third
8 sentence, and it reads: "Studies of the same
9 issue in different databases, however, can
10 and do generate different results, sometimes
11 with strikingly different clinical
12 implications."

13 And then, "In this paper,
14 we're systemically studying heterogeneity
15 among databases," correct?

16 A The impact of database
17 heterogeneity, yeah.

18 Q Okay.

19 And your conclusion was that
20 clinical studies that use observational
21 databases can be sensitive to the choice of
22 database, and more attention is needed to
23 consider how the choice of data source may be
24 affecting results, correct?

25 A You read that correct.

1 Q Okay.

2 Now, moving into the actual
3 portion of the article, the first paragraph,
4 midway down, you state: "Many potential
5 biases and sources of variability threaten
6 the validity of such studies, and a
7 substantial literature documents these
8 concerns."

9 Correct?

10 A Yes.

11 Q All right.

12 And is that still your opinion
13 today?

14 A Sure.

15 Q And then at the bottom of that
16 column, you say: "Recent meta-analyses of
17 observational studies have shown that
18 individual studies of the same drug effect
19 yielded conflicting results ranging from
20 statistically significant decreased risk to
21 statistically significant increased risk."

22 Correct?

23 A You read that correctly.

24 Q Okay.

25 And so from a layperson's

1 perspective, is what you're saying that
2 essentially when you're looking at
3 meta-analyses of observational studies,
4 you -- if you don't control for
5 heterogeneity, you will end up with different
6 results from different studies?

7 A No.

8 MR. NIGH: Object to form.

9 A That is absolutely not what it
10 says.

11 So it says that when you're
12 doing -- there are meta-analyses out there
13 where some of the component studies of that
14 meta-analysis can be statistically
15 significant in one direction, and within the
16 context of the same meta-analysis, you can
17 have something that's statistically
18 significant in the other direction.

19 It didn't happen here, I would
20 point out. But can that happen? Yes, that
21 can happen.

22 Q That's a risk of using
23 observational studies to draw conclusions,
24 correct?

25 A No, no, it's not a risk. It's just

1 a fact. It can happen. And it's one of the
2 reasons -- it's one of the motivations for
3 doing meta-analysis, is to arrive at kind of
4 an omnibus picture of what's going on.

5 Q Well, it's one of the concerns that
6 you raise in your paper about observational
7 studies, correct?

8 A This paper is not about
9 meta-analysis, and this paper is about
10 database -- first of all, it's about database
11 studies. We don't have database studies in
12 this context here, in the context of
13 valsartan. We're not talking about database
14 studies.

15 This is a paper about database
16 studies, claims databases and electronic
17 health records databases, and it's making the
18 point that the database itself can be a
19 source of heterogeneity. That's the point of
20 the thing.

21 Q Okay.

22 And if you look at page 647,
23 in your Discussion section, you do talk about
24 database studies, and you say: "Our findings
25 suggest that 20 percent to 40 percent of

1 observational database studies can swing from
2 statistically significant in one direction to
3 statistically significant in the opposite
4 direction depending on the choice of
5 database, despite holding study design
6 constant."

7 Correct?

8 A You read it correctly.

9 Q Now, when you turn to page -- the
10 very last page of the article, the next to
11 the last -- actually, the last paragraph
12 before the acknowledgments you state: "We
13 believe our findings have two immediate
14 implications. First, when interpreting
15 results from a single observational data
16 source, more attention is needed to consider
17 how the choice of data source may be
18 affecting results."

19 Did I read that correctly?

20 A You did.

21 Q "Second, where possible, studies
22 should examine multiple sources to confirm
23 that significant findings are consistently
24 identified, or that results are at least
25 consistent across databases."

1 A I see that.

2 Q "When interpreting results across
3 multiple sources, it is important to
4 characterize the observed heterogeneity and
5 limit the use of composite estimates that
6 could otherwise hide the uncertainty in
7 effect estimates that is not driven by
8 sampling variability."

9 A You read that correctly.

10 Q I read that correctly?

11 And you agree with these
12 statements, although your position is they
13 don't apply to the papers that you reviewed
14 for valsartan.

15 Is that my understanding?

16 A Not directly. Because these are --
17 this is about database studies, claims
18 databases, EHR databases, where you have many
19 options that you might consider.

20 These are studies that were
21 designed to address a particular question.
22 They're dietary studies involving
23 questionnaires and so on. They're of a
24 completely different nature.

25 MR. NIGH: Object to the form

1 of that last question.

2 Q Those -- they are of a completely
3 different nature but the issue or the concern
4 with regard to heterogeneity is still at play
5 in those types of studies, even if it's not a
6 large database or a pharmacovigilance
7 database. Wouldn't you agree with that?

8 MR. NIGH: Object to form.

9 A As a general matter, in particular
10 when you're doing meta-analysis, one of the
11 things you consider is heterogeneity, and
12 that's exactly what I did here in the comment
13 in the report about it, about the context of
14 the Song meta-analysis.

15 So sure, yeah, heterogeneity
16 is something that one thinks about.

17 Q Right.

18 And in the -- your comment on
19 the Song meta-analysis on page 3 of your
20 report, you say -- and this is with respect
21 to gastric cancer: "Song included 11 studies
22 concerning NDMA and gastric cancer and
23 yielded a relative risk estimate of 1.34 and
24 an associated 95 percent confidence
25 interval."

1 You then -- end of that
2 paragraph, you say: "There was, however,
3 considerable between-study heterogeneity,"
4 correct?

5 A Yes.

6 Q Okay.

7 And what is the concern or the
8 reason for the comment that there was
9 considerable between-study heterogeneity in
10 that meta-analysis?

11 A So the I^2 , which is a measure of
12 heterogeneity, if my memory is right, is
13 around .7. That's moderately high, so the --
14 there's a certain amount of heterogeneity
15 here. It's certainly not extreme.

16 It's not extreme in the sense
17 that you've got studies in there that are
18 statistically significant in one direction
19 and others that are statistically significant
20 in the other direction. But nonetheless, as
21 you look at this and interpret it, there's a
22 fair amount of heterogeneity amongst these
23 studies.

24 Q And, in fact, it was considerable
25 enough that you felt obligated to mention it

1 in your report, correct?

2 MR. NIGH: Object to form.

3 A Evidently so.

4 Q So the paper that you actually
5 cited in your report on footnote 8, let's get
6 that marked as well.

7 So we are up to 18, I believe.

8 (Exhibit 18 marked for
9 identification.)

10 BY MS. LOCKARD:

11 Q For the record, this is "A Systemic
12 Statistical Approach to Evaluating" --

13 A Systematic.

14 Q It says a system -- oh, "Systematic
15 Statistical Approach to Evaluating Evidence
16 from Observational Studies." Okay.

17 And this is the paper authored
18 by you that you cited in your report,
19 correct?

20 A Coauthored by me, yes.

21 Q Okay.

22 If you turn to the abstract
23 section on the first page, if you'll follow
24 along with me, it says: "Threats to the
25 validity of observational studies on the

1 effects of interventions raise questions
2 about the appropriate role of such studies in
3 decision-making."

4 Is that what it says there?

5 A Yes.

6 Q And then you go on at the end of
7 the abstract to explain: "Here, we review
8 some of the challenges encountered in
9 observational studies and review an
10 alternative, data-driven approach to
11 observational study design, execution, and
12 analysis."

13 Correct?

14 A Yes.

15 Q What -- just in sort of basic
16 terms, what was the alternative, data-driven
17 approach that you were recommending in this
18 paper?

19 A So if you turn to -- if you turn to
20 Section 5, we describe -- in this paper, we
21 describe an alternative -- an alternative
22 approach.

23 Q Which is what?

24 A Give me an hour and I'll tell you.
25 I mean, it's not so simple.

1 (Laughter.)

2 A I'm not giving you an hour.

3 (Laughter.)

4 A I mean, it involves -- okay.

5 Loosely, it involves the use of negative
6 controls. As I said, there are many pieces
7 to it, but one piece of it is -- involves the
8 use of negative controls.

9 So the idea is you want to
10 study the association between A and B and you
11 find things that are known to not -- known
12 causally to not be associated with A and are
13 not associated with B. They are called
14 negative controls.

15 And the basic idea is you
16 build a so-called empirical null distribution
17 from those negative controls and use that to
18 compute calibrated p-values and confidence
19 intervals.

20 So it's a proposed approach
21 that we, myself and my colleagues, have now
22 used and published many such studies in the
23 literature.

24 To state the obvious, you need
25 the data to do this. You cannot do that kind

1 of analysis in the context we're discussing
2 here.

3 Q Right.

4 Because the data in the
5 context of valsartan in pharmaceuticals
6 doesn't exist to allow you to apply your
7 alternative methodology, correct?

8 MR. NIGH: Object to form.

9 A I don't know about doesn't exist,
10 but I don't have it.

11 Q So in Section 5, you also say:
12 "The consumer of the resulting analysis must
13 rely on the professional experience and
14 reputation of the analyst to assess the
15 weight of evidence to attach to the study."

16 Do you see that?

17 A Sure.

18 Q Is that in reference to your
19 alternative approach?

20 A No.

21 Q That's with respect to
22 observational settings, correct?

23 A Well, let's look at the context.

24 So, "Current strategies" --
25 I'm reading from the paper.

1 "Current strategies for the
2 design of observational studies rely heavily
3 on the expertise of analysts. Process of
4 expert consideration, introspection, anecdote
5 and discussion leads to a particular design.
6 The consumer of the resulting analysis must
7 rely on the professional experience and
8 reputation of the analyst to assess the
9 weight of evidence to attach to the study."

10 That describes the kind of
11 current state of play, including in -- in the
12 context we're discussing here today.

13 Q And then it goes on to say:
14 "Because little empirical evidence exists to
15 support this process, subjective assessment
16 of new results along with prior release about
17 the reliability of observational studies
18 dominates the interpretation of observational
19 findings and current practice," correct?

20 A You read that correctly.

21 Q And you would still agree with that
22 today, correct?

23 A Yeah, I mean, I -- in this
24 particular context, I am analyzing a set of
25 observational studies, and I am using my

1 expertise and my -- my judgment to draw
2 conclusions.

3 Q And then a couple of sentences
4 later, you say: "Future work can lead to
5 improvements in methods that may have better
6 performance, but our findings suggest that
7 empirical evidence will be required to
8 justify interpreting observational analyses
9 properly."

10 A Yeah. You read that correctly.

11 Q Okay.

12 In this case, with respect to
13 valsartan, you don't have empirical evidence
14 corroborating the observational studies that
15 you've relied on, correct?

16 A Not of the type that's envisioned
17 in this paper, nor is it conceivable in this
18 context.

19 Q Right.

20 So the type of empirical
21 evidence that you are recommending in this
22 paper you do not have for valsartan, right?

23 A So, conceivably, if this -- this
24 is -- you know, not a practical proposition.

25 If one had access to the raw

1 data in every one of these studies, it's
2 conceivable you could do some of the things
3 that are described in this -- in this recipe,
4 but I don't, and I don't think it's feasible.

5 I will say this: What we're
6 proposing in this paper is, you know, we are
7 proposing this to the world and hoping that
8 the world, you know, adopts it. This is
9 not -- this is not standard.

10 Q Right.

11 This is what you're proposing
12 as the alternative? It's not an accepted
13 methodology as of yet, correct?

14 MR. NIGH: Object to form.

15 A Not in widespread use, is how I'd
16 put it.

17 Q But, I mean, there are other quotes
18 in here, and I can read from them, you know,
19 about challenges and observational analyses
20 and, you know, mainly mentioning insufficient
21 sample size, lack of applicability to
22 reliably estimate the risk of many potential
23 safety concerns for the target population.

24 "And even if one leverages
25 meta-analytic tools, rare side effects,

1 long-term outcomes, both positive and
2 negative, and effects in patients with
3 comorbidities may still be unknown when a
4 product is approved because of the relatively
5 small size and short break in clinical
6 trials."

7 A The common -- the question I was
8 just asked pertains to clinical trials.

9 Q Clinical trials.

10 A Completely different context.

11 Q Right.

12 The comment I just read
13 doesn't apply to occupational studies at this
14 point, right?

15 A I believe so. I don't even know
16 where it is, but I don't -- I don't believe
17 it does.

18 Q I think I misread the wrong
19 section. I apologize.

20 I'm on page 15 now. And at
21 the top of the first full paragraph, it says:
22 "The principal concern for all observational
23 studies, which is of particular relevance in
24 observational database evaluation, is the
25 potential for bias."

1 That does apply to
2 occupational studies, correct?

3 A Sure, yes. The overarching concern
4 is one of bias, particularly in this case,
5 for example, if there's real possibility of
6 bias to the null, that's a type of bias I was
7 concerned about.

8 Q Likewise -- and I know you've given
9 testimony on this issue before with respect
10 to challenges of observational studies.

11 Do you recall testifying about
12 that --

13 A You need to --

14 Q -- in the -- let me direct you to
15 Thibodeau deposition in Taxotere.

16 A Okay.

17 Q You recall that being a line of
18 questioning in your deposition, November 14,
19 2019?

20 A I'm not that good. I do not
21 recall.

22 Q Do you remember giving a deposition
23 in Thibodeau, a Taxotere case, in November of
24 2018?

25 A I don't remember the name of the

1 plaintiff, but we could look up and see if
2 that's one of the -- that's on the list that
3 I did. I'm sure it is. I don't doubt it.

4 Q Let me ask you this:

5 So do you agree that
6 observational studies can be challenging
7 because of different biases that may distort
8 the true effect, i.e., systematic error,
9 recall bias, selection bias, response bias,
10 therapy bias and confounding?

11 A That's -- that's --

12 MR. NIGH: Object to form.

13 A -- kind of a sweeping generality.
14 Sure, yeah. I mean, observational studies
15 differ from a randomized trial, so there are
16 concerns that arise in observational studies.
17 That -- that statement lists a few of them.

18 Q Where does an observational study
19 fall on the hierarchy of evidence?

20 A So you asked that question as if
21 there's a single hierarchy of evidence that
22 the whole world agrees on. There isn't.
23 But -- but I think in just about anyone's
24 hierarchy, below randomized trials.

25 Q Okay.

1 All of the studies that you
2 looked at that were referenced in your report
3 were observational studies; were they not?

4 A Yeah. It doesn't seem likely that
5 we're going to have randomized trials in this
6 area anytime soon.

7 Q Right.

8 That's a challenge, because
9 you don't have the availability to do that,
10 and there would be concerns with patients if
11 you tried to set up such trial, correct?

12 A Absolutely, yes. Giving --
13 randomizing people to a carcinogen is not
14 going to happen, thankfully.

15 There's nothing unusual about
16 this. There are many, many questions in
17 healthcare where the only evidence we have is
18 observational in nature.

19 It's not like this is a
20 bizarre outlier. This is, in fact, more the
21 norm.

22 Q And so, you know, in your paper,
23 you recognize that there are limitations --
24 strike that.

25 In your expert report, you

1 recognize that there are limitations of
2 observational studies, yet you go on to rely
3 on observational studies.

4 A And I publish them. I do them
5 myself, many of them.

6 MR. NIGH: Object to form.

7 A The healthcare system needs
8 evidence, right? It's the raw -- the fuel
9 that kind of drives the healthcare system.
10 Much of that evidence by necessity derives
11 from observational studies.

12 Now, my work -- my research
13 work is trying to find always ever-better
14 ways of doing that. But be that as it may,
15 we rely on observational studies.

16 I publish them. The world
17 relies on them.

18 Q So likewise, though, you took a
19 look at the Pottegard study, which was the
20 only study in your file that actually relates
21 to nitrosamine exposure in pharmaceuticals,
22 and you described for us earlier the
23 limitation of that study, correct?

24 A Sure, yeah.

25 Q But you didn't include that study

1 with or without its limitations in your
2 report even though you reviewed it?

3 A It wasn't germane to the question I
4 was being asked.

5 Q Is it not germane to the question
6 at issue in this litigation regarding whether
7 or not nitrosamines at the levels found in
8 valsartan cause cancer?

9 MR. NIGH: Objection.

10 A That's not the question I was asked
11 to address. So the question I was asked to
12 address was to look at studies that
13 quantified the effect numerically of certain
14 amounts of NDMA.

15 That's not -- that's not
16 what's happening in Pottegard.

17 Q Well, if it wasn't germane to the
18 question you were asked, why do you have the
19 paper, the response and many other documents
20 in your file all related to Pottegard?

21 A I was interested, and I looked at
22 it and studied it and formed opinions that I
23 shared with you. But it's not germane to the
24 particular question I was asked here, hence
25 it's not featured in my report.

1 Q Well, it's not featured in your
2 report because it's not consistent with your
3 conclusion in your report.

4 Isn't that the truth?

5 MR. NIGH: Object to form.

6 A That's -- as I just explained to
7 you this morning, it is in very many ways
8 very problematic. I consider it the
9 opposite, actually.

10 You know, it's very
11 problematic with regard to the effect of --
12 the association between contaminated
13 valsartan and cancer.

14 So no, I -- what you said is
15 false. And the reason I didn't include it
16 was it wasn't germane to the question I was
17 asked to study, and therefore I didn't
18 include it.

19 But as you saw this morning, I
20 am more than happy to share my opinions.

21 Q Well, and I understand that you
22 believe there are some limitations, and you
23 explained this very clearly.

24 But there is some disconnect
25 that I'm trying to understand where you also

1 have spent a career explaining the
2 limitations of observational studies, yet you
3 find them reliable and germane enough to
4 include in your report.

5 MR. NIGH: Object to form.

6 A Not in full generality. There are
7 some observational studies that I will
8 happily rely on, subject to limitations.
9 There are others that I feel are fatally
10 flawed, and that --

11 The good news with Pottegard
12 is I think their overall analysis is highly
13 problematic, but they did do a new user --
14 happily, they did do a new-user analysis,
15 which I do think is a reliable piece of
16 evidence.

17 Q But the new-user analysis, I
18 believe you testified, was not statistically
19 significant, right?

20 A So -- so what? Like, really?

21 The confidence interval begins
22 at .99 --

23 You're going to say the
24 confidence interval because it begins at .99
25 as against 1.01, we're good to go? There

1 isn't a problem?

2 You've got to be kidding me.

3 Q So let's -- I just want to identify
4 within your file that we were produced
5 yesterday --

6 MS. LOCKARD: We'll mark these
7 as Exhibit -- what are we up to?

8 MR. NIGH: 19, I think.

9 MS. LOCKARD: 19. You're
10 better at this than we are.

11 (Exhibit 19 marked for
12 identification.)

13 BY MS. LOCKARD:

14 Q Okay.

15 So this is the collection of
16 materials that were included within a file
17 folder labeled "Pottegard."

18 So I'll just ask you -- we'll
19 make all of this Exhibit 19, and then we'll
20 just go through these one by one, and you can
21 explain to me what they are.

22 Let's start with the paper,
23 which I believe is this. You can correct me
24 if I'm wrong, but is that the Pottegard
25 paper?

1 A You actually gave me two papers.

2 Let me give that back.

3 Q Yes.

4 A So this is the paper, yes.

5 Q Okay.

6 So you read that paper. It
7 was in your file, right?

8 A Right.

9 Q That's the paper you've been saying
10 is flawed?

11 A I said something more nuanced than
12 that. I said their main analysis is very
13 problematic, but there's an analysis in here
14 that is much -- I think is much more apropos.

15 Q Okay.

16 But even their new analysis is
17 not germane to the question you were asked.
18 That's why it's not in your report, right?

19 MR. NIGH: Object to form.

20 A Right. Because it didn't quantify
21 the amount of NDMA.

22 Q Okay.

23 So what I want to do is to
24 hand you -- so there are an additional five
25 documents that pertain to Pottegard.

1 Can you just explain to us for
2 the record what these five documents are?

3 A Sure. I can try.

4 So one of them is
5 supplementary material to the published
6 paper.

7 Q Published by Pottegard, right?

8 A Right.

9 Another one appears to be --
10 another one appears to be letters -- excuse
11 me, letters published in that journal about
12 this paper. I have no recollection of
13 looking at that.

14 Q Okay.

15 A Actually, two of them appear to
16 be -- are they the same? No, they're not.

17 These appear to be letters
18 of -- I don't know if they were published or
19 not, but letters about this paper, is what
20 they appear to be. I have no memory of
21 looking at these.

22 And then the other two are
23 correspondence between -- they're the reviews
24 of the paper. Actually, one of them is the
25 reviews of the paper with the author's

1 response interspersed.

2 Q Did you look at that?

3 A Yeah.

4 Q And you've reviewed the supplement
5 material by Pottegard?

6 A I don't recall.

7 (The deponent read the
8 document.)

9 A Yeah. So this is correspondence,
10 you know, between the authors and the
11 journal. Both of these are correspondence
12 between the author and the journal. I
13 believe I've looked at both of these.

14 Q If you will, can I have the
15 Pottegard article and the supplement? I
16 just -- I've got to make the record clear.

17 So we've made these
18 collectively Exhibit 19, but we'll make --
19 we'll make the actual article you spoke about
20 first 19A; the supplement, 19B; the two
21 letters that you said you did not review --

22 A No, I didn't. I said -- I don't
23 know. They just don't look familiar to me
24 this minute.

25 (Exhibit 19B marked for

1 identification.)

2 BY MS. LOCKARD:

3 Q Okay.

4 So --

5 A And they're not two letters. I
6 think there's more than -- they're several
7 letters in there.

8 Q Okay.

9 One was a letter -- this is
10 one letter to the editor, and you don't know
11 if you reviewed this?

12 A Yeah, I haven't looked at these for
13 whatever it is, two or three months. I --
14 that doesn't instantly look familiar to me,
15 so I don't know if I did read.

16 Q I'm going to make that 19C. You
17 don't know if you read that.

18 (Exhibit 19C marked for
19 identification.)

20 (Exhibit 19D marked for
21 identification.)

22 BY MS. LOCKARD:

23 Q The 19D is --

24 A "Letters," plural, right.

25 Q "Letters," plural. And you don't

1 know if you read these, correct?

2 A Not sure. If I read them and
3 talked about them now, I might recall
4 something or I might not. I don't know.

5 Q Okay.

6 And one of the letters in 19D
7 was -- there's a letter and a response, and
8 that's between the author and Dr. Etminan,
9 correct?

10 A I have no idea.

11 Q Do you recall that?

12 A No.

13 I mean, I'm sure you're
14 telling the truth, but I don't recall that.

15 Q Well, it says, "Dear Drs. Etminan
16 and Mansournia."

17 A Okay.

18 Q So before me just saying that, you
19 didn't know that these letters were with --
20 at least one of them was with Dr. Etminan?

21 A I -- I have no recollection of
22 that. Maybe I knew that. Maybe I didn't. I
23 don't know.

24 Q Did you get these materials from
25 Dr. Etminan?

1 A No.

2 Q Did you get them from plaintiffs'
3 counsel?

4 A Yes.

5 (Exhibit 19E marked for
6 identification.)

7 (Exhibit 19F marked for
8 identification.)

9 BY MS. LOCKARD:

10 Q Okay.

11 And these two, which we'll
12 make 19E and 19F --

13 A Yeah.

14 Q -- you said you did review these?

15 A Yeah.

16 Q Did anybody tell you not to include
17 the Pottegard paper in your report?

18 A No.

19 Q Okay. So let's turn back to your
20 actual report.

21 All right. The last sentence
22 of paragraph 8, you say: "For each study I
23 compute the mean 'lifetime cumulative
24 exposure' (the LCE) as the average number of
25 days from birth to study end multiplied by

1 the lower bound of the NDMA (or NDEA) daily
2 level in the highest group. In studies
3 presenting multiple analyses I focused on the
4 maximally adjusted analyses."

5 Did I read that correctly?

6 A Yes.

7 Q Can you explain what the maximally
8 adjusted analyses is?

9 A Sure.

10 So in some papers, not all,
11 but in some of the studies, they present
12 analyses that are unadjusted; and then
13 sometimes analyses that are adjusted for,
14 let's say, age and sex; and then sometimes
15 they present an analysis in addition
16 adjusting for age, sex, and several other
17 things.

18 So I -- as a matter of my
19 approach to this in such matters is to use
20 the maximally adjusted one, the one that has
21 the most variables adjusted.

22 Q Did you -- did you consider making
23 any adjustments for any confounding factors
24 in any of these reports?

25 A So I don't get -- I don't have the

1 data, so I don't get to do these analyses.

2 I'm relying on the author's analysis.

3 But, in general, their
4 attempts -- their adjustments are attempts to
5 control for confounding.

6 Q Did you reach any conclusions about
7 whether the authors adequately control for
8 confounding factors in any of the dietary
9 studies?

10 A It all seemed reasonable to me. I
11 looked at each one of them. Without access
12 to the data, there's only so much you can do.

13 It seemed reasonable to me,
14 what they did.

15 Q So if you look at the next section,
16 the gastric cancer section, you talk about
17 the meta-analysis by Song, including 11
18 studies concerning NDMA and gastric cancer
19 yielded a relative risk estimate of 1.34.

20 And then the next paragraph,
21 you say: "I note that Loh reports stomach
22 cancer hazard ratio of 1.13."

23 Correct?

24 A You read that correctly.

25 Q And then you say: "Adding Loh to

1 the Song meta-analysis yields an estimate of
2 1.32 and a slightly lower" --

3 A I².

4 Q Okay.

5 So essentially what you're
6 saying is you're combining summary measures
7 of the relative risk estimate in the cancer
8 hazard ratio.

9 Is that right?

10 A I --

11 Q You're combining those --

12 A Why did you put the word "cancer"
13 in there? I'm confused.

14 Q Because you say: "I note" -- this
15 is paragraph 10.

16 "I note that Loh reported a
17 stomach cancer hazard ratio of 1.13."

18 A Can I try and simplify this, if I
19 might?

20 Q Sure.

21 A So in these studies, generally
22 speaking, there are effect estimates. That's
23 why I'm focusing on them. And the effect
24 estimates are generally of one of three
25 types: Relative risks, odds ratios, hazard

1 ratios.

2 Actually, I don't know that
3 they're relative risks. I'm not even sure
4 all three are represented, but there are
5 certainly odds ratios and hazard ratios.

6 So in the Song meta-analysis,
7 they are already doing a meta-analysis across
8 odds ratios and hazard ratios, treating them
9 as effect sizes.

10 They have slightly different
11 meanings, but it's quite common, as Song did,
12 to do meta-analysis across hazard ratios and
13 odds ratios and relative risks.

14 Q Okay.

15 A So that's what they did. I just
16 added one more to the mix.

17 Q But odds ratios are basically black
18 and white. You got cancer or you didn't.

19 Correct?

20 MR. NIGH: Object to form.

21 A They're -- well, they're odds
22 ratios. They refer to the odds of getting
23 cancer as a function of whether you can treat
24 it or not.

25 It's a ratio of odds ratios,

1 and it comes out of a logistic regression.
2 And hazard ratios are derived differently,
3 but they're effect sizes. They amount to an
4 estimate of the increased risk.

5 Song combines them. Some of
6 the studies have odds ratios. Some of the
7 studies have hazard ratios. It's routine to
8 do meta-analysis across those different
9 measures.

10 Q And hazard ratios take into account
11 the time factor as well, right?

12 A So can logistic regression, meaning
13 it can account for time. It's not a unique
14 characteristic of Cox regression, but the --
15 I think the more --

16 I think the point that you're
17 circling around is putting them together.
18 And my point was yes, I put them together.
19 And Song had already done that, and it's
20 relatively -- you see that all the time in
21 the literature.

22 Q And so you say that's an accepted
23 method to combine those two summary measures?

24 A Yeah, it's routine.

25 Q And then similarly, paragraph --

1 well, is it Cui and Rogers?

2 A Yeah.

3 Q So in the esophageal section,
4 again, you say: Cui has a meta-analysis
5 which found an increased risk of esophageal
6 cancer associated with NDMA, and there's a
7 hazard ratio of 1.18.

8 And then in the next
9 paragraph, you say: "Cui appear not to have
10 included Rogers."

11 A Okay.

12 MR. NIGH: Object to form.

13 Q I mean, is that right? That's
14 right, right?

15 A You read it correctly.

16 Q Cui didn't include Rogers.

17 But so then you've combined
18 Rogers with Cui to come up with your
19 conclusion in paragraph 12?

20 A The same -- same answer. It's --
21 there's nothing unusual about that. I am --
22 yeah, one of them has -- there's -- one of
23 them is a hazard ratio. There are, I think,
24 four studies in Cui, and they report a hazard
25 ratio, and then I'm combining that with an

1 odds ratio.

2 It's the same answer as the --
3 the discussion we just had about Song.

4 Q Right.

5 And I'm just pointing out,
6 this is another instance where you combine
7 the summary measures, but you -- but your
8 position is that that's totally acceptable,
9 correct?

10 A Yeah, it's -- it's done, you know.

11 Q All right.

12 And Song itself -- so that was
13 a gastric cancer which relied on
14 self-reported dietary information from
15 questionnaires, right?

16 A I think that's true for all of the
17 component studies, yes.

18 Q And so obviously the information
19 that's relied on in Song or the other studies
20 is only as useful as the information that's
21 provided through the questionnaires?

22 MR. NIGH: Object to form.

23 A I have no idea.

24 Q Is that fair?

25 A I have no idea what you mean by "as

1 useful as."

2 Q Well, have you ever seen any
3 reports or studies about the lack of
4 reliability questionnaire reporting in
5 studies?

6 MR. NIGH: Object to form.

7 A Sure, including, you know, when I
8 cited -- at least concern with bias towards
9 the null because of the nature of the way the
10 data are gathered.

11 Q So my point is that if the
12 information is gathered from a questionnaire
13 which is known to have bias built in, then it
14 is going to potentially impact the
15 reliability of the study results, correct?

16 MR. NIGH: Object to form.

17 A I mean, that -- you said -- I think
18 you used the phrase "known biases," and I
19 don't think we know the nature of any bias in
20 any one of these studies in particular or
21 specifically.

22 You know, as a general matter,
23 one worries about bias in observational
24 studies, as we've talked about. And, yeah,
25 you know, when you're gathering data via

1 questionnaire, there are recall biases that
2 you worry about.

3 You know, arguably, these are
4 generally biases towards the null, but -- but
5 certainly, you know, these are things one
6 worries about.

7 Q Okay.

8 And so just simply put,
9 that -- biases such as recall biases from
10 questionnaires that are used in these types
11 of dietary studies that you relied on here is
12 one potential concern with relying on these
13 studies?

14 MR. NIGH: Object to form.

15 A Sure. Insofar as there are
16 concerns about recall bias. And recall --
17 actually, forget bias for a second. Just
18 concerns about how well people can recall
19 these things, that's a concern, sure.

20 Q So the gastric study -- the only
21 two gastric studies you looked at were Song
22 and Loh.

23 Is that correct?

24 A No. So I looked at the component
25 studies of Song.

1 Q Okay.

2 So you looked at the actual
3 component studies of Song. You said that
4 earlier, correct?

5 A Yes.

6 Q Are those part of what was
7 contained within your file?

8 A Should be, yes.

9 MR. NIGH: Object to form.

10 A Actually, let me be more
11 definitive. "Yes," rather than "should be."
12 They are in there.

13 Q They are in there.

14 (Pause.)

15 A And actually, they are -- and they
16 are in Table 1.

17 Q Okay.

18 Table 1 on page 7?

19 A Yeah.

20 Q Right.

21 On Table 1, did you consider
22 making an adjustment for the multiple
23 comparison problem?

24 MR. NIGH: Object to form.

25 A Multiple comparison problem. I

1 mean, I did not adjust -- there's no
2 adjustment for multiplicity here, nor would
3 I -- would I think it's even remotely
4 appropriate.

5 Q Why not?

6 A This is a safety issue, so there's
7 kind of a fundamental tension between, you
8 know, multiplicity correction and safety.

9 So multiplicity corrections,
10 you know, there are various kinds out there.
11 You know, what they do is they focus on
12 so-called type one error, so they -- they put
13 an extreme cap on the chance of making a type
14 one error, which is a false signal.

15 So what they do is they
16 literally destroy statistical power. That's
17 what they do. They reduce the statistical
18 power of the analysis in order that you keep
19 a tight lid on the type one error rate.

20 That's the opposite of what
21 you want to do with safety. With safety, you
22 want to know about a safety problem if
23 there's one there. And in general, for
24 example, in clinical trials, multiplicity
25 adjustment for safety endpoints is -- is --

1 is not -- is very unusual. It's not -- it's
2 not what the normal practice is.

3 So, you know, for any one of
4 these -- I'm pointing to Table 1.

5 For any one of these studies,
6 if the p-value is less than .05, that study
7 is statistically significant. Period. Full
8 stop.

9 And the fact that there are
10 other studies on the table doesn't in any way
11 take -- diminish that fact. I can go on and
12 on. I won't.

13 Q If -- if you -- if you had made an
14 adjustment for the multiple comparison
15 problem, would the p-value have the -- the
16 question -- well, strike that.

17 If you had applied a .0003
18 rather than a .05, would that have resulted
19 in a change in the SS column, for statistical
20 significance?

21 A Sure. I mean, that's a tautology.
22 You're saying if you did something
23 inappropriate, I consider inappropriate, if
24 you did that, would it reduce the number of
25 things that were statistically significant.

1 Of course.

2 As a matter of fact, you could
3 set the threshold to zero and nothing would
4 be statistically significant.

5 Q Correct.

6 A Knock yourself out, but it doesn't
7 make any sense.

8 Q Right.

9 But if you -- if you did apply
10 a .0003 rather than .05, then virtually none
11 of these studies would have shown statistical
12 significance, right?

13 A Again, the premise seems absurd to
14 me, but we actually don't know that, because
15 for a bunch of them, it's just less than --
16 I'm looking at the P for trend.

17 Q Yeah, so we wouldn't know for
18 DeStefani --

19 A For trend in particular.

20 Q -- or Zheng -- no, actually, Zheng
21 would be -- well, I guess -- let me -- I'm
22 sort of talking out of turn.

23 The ones that have less than
24 you're saying you wouldn't necessarily know.

25 A Strictly speaking, yeah, we don't

1 know. We don't know what the p-value
2 actually is.

3 Q So even using the .05, the SS
4 column for statistical significance, for each
5 and every one of the cancers that was covered
6 in these studies in the table, there's at
7 least one study that was not statistically
8 significant, right?

9 A True.

10 Q And for bladder, there's only one
11 study, and it wasn't statistically
12 significant, right?

13 A Sure.

14 Q And then for prostate, there are
15 two studies, and neither of them is
16 statistically significant, right?

17 A Sure.

18 Q And then for esophagus, there are
19 four studies, and three out of four are not
20 statistically significant?

21 A Sure. I'm wanting to say "so
22 what," but I'm not allowed to do that, so I
23 won't.

24 Q So the Zheng study that you looked
25 at, that was the only study in your report

1 that involved NDEA, correct?

2 A That is correct.

3 So that was the only study
4 that I had that quantified an NDEA of that
5 size.

6 Q Did you look for any additional
7 NDEA dietary studies outside of what you were
8 provided by counsel?

9 A Well, that goes back to a
10 conversation we had earlier.

11 I started with the -- you
12 know, the studies that came out of
13 Dr. Etminan's search, and I did look at
14 references in those papers to see if there
15 was anything that was not included in that
16 set, and that would have included NDEA.

17 Q Just so we can get -- take a look
18 at that.

19 MS. LOCKARD: So we'll mark
20 this as 20.

21 (Exhibit 20 marked for
22 identification.)

23 BY MS. LOCKARD:

24 Q So this, I believe, is the Zheng
25 paper, which is the NDEA paper?

1 A It has both.

2 Q And it has both.

3 But it's the only paper that
4 addresses NDEA in your file, correct?

5 A Is that a true statement? It might
6 be. It's the only one that quantified --
7 quantifies NDEA and the effect of it.

8 Q Well, it's the only paper
9 addressing NDEA that you relied on in your
10 expert report, right?

11 MR. NIGH: Object to form.

12 A I think that's a true statement.
13 It's the only one in Table 1 for sure.

14 Q So there are a number of references
15 in Zheng at the last two pages, that are
16 additional papers that do address NDEA, I
17 believe.

18 A So I looked at these. I don't
19 think any of them quantified the amount of
20 NDEA in their analysis.

21 Q So did you look at all of the --
22 this is just -- just trying to clarify.

23 Did you actually look at all
24 of the papers that are listed in the
25 references 1 through 43?

1 A Yes.

2 Q And there was nothing that you saw,
3 whether it quantified or not, NDEA that you
4 felt that was germane to include it in your
5 report?

6 A No, hang on. It wouldn't have been
7 germane if it didn't quantify the amount of
8 NDEA.

9 So I didn't find anything in
10 any of these references -- any of these
11 papers, I didn't find anything in the
12 references that rose to the level, so to
13 speak, that it should be included.

14 Am I being clear?

15 Q I think so. I get your point. I
16 take your point.

17 And Zheng was also the only
18 study you looked at that addressed pancreatic
19 cancer.

20 Is that right?

21 A Yes.

22 Q So I notice that in your report,
23 you don't address any studies involving lung
24 cancer.

25 Why is that?

1 A Yes, I do.

2 MR. NIGH: Object to form.

3 Q Excuse me. Let me strike that.

4 You're right. I'm not trying to pull a fast
5 one.

6 You didn't refer to any
7 studies involving breast cancer. That's
8 correct, right?

9 A I don't recall there being breast
10 cancer in any of the studies that were --
11 remember, my starting point is Dr. Etminan's,
12 you know, search. I don't believe there were
13 any breast cancer studies in there that
14 quantified the amount of NDMA or NDEA.

15 Q There -- the plaintiffs in this
16 case submitted a disclosure of cancers at
17 issue in the litigation.

18 Have you ever seen that
19 document?

20 A No.

21 Q So as you sit here in the
22 deposition, you're not aware of what specific
23 cancers plaintiffs had disclosed as being at
24 issue in the MDL?

25 A I am not. I am not familiar with

1 that.

2 MR. NIGH: Object to form.

3 Q So the list of cancers that you
4 have in your paper -- gastric esophageal,
5 pancreatic, lung, colorectal, prostate,
6 bladder -- is that a list that was provided
7 to you by counsel when you were asked to look
8 at the case?

9 A No. So this is a function of the
10 studies. Do you know what I mean?

11 Q I know what you mean, okay.
12 So plaintiff asked you to look
13 at the studies. These are the cancers that
14 were addressed in the study?

15 A Yeah. And Hidajat has other ones.

16 Q Okay. We'll get there.

17 I guess since your report
18 doesn't address breast cancer, you don't have
19 any opinions about breast cancer or
20 statistical opinions about breast cancer?

21 A As it relates to contaminant
22 valsartan, no, I do not.

23 (Pause.)

24 Q So the Cui paper we were talking
25 about, the Cui paper --

1 A Mm-hmm.

2 (Pause.)

3 Q All right. Let's get that marked,
4 Exhibit 20 [sic].

5 (Exhibit 21 marked for
6 identification.)

7 BY MS. LOCKARD:

8 Q All right. So can you identify 20,
9 Exhibit 20? Is that the --

10 MR. NIGH: 21.

11 MS. LOCKARD: Got to keep it
12 straight, Steve.

13 BY MS. LOCKARD:

14 Q So 21, is that the Cui paper?

15 A Yes.

16 Q All right.

17 And this is the version that
18 was in your file, I believe, correct?

19 A Looks like it.

20 Q It's in Chinese.

21 Do you speak or read Chinese?

22 A No.

23 Q Okay.

24 Were you able to get this
25 translated to English?

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1 A No, but the abstract is in English.

2 Q Okay.

3 So in terms of the Cui paper,
4 you only reviewed the abstract?

5 A No. The -- there's a table on
6 page 728 that lists the studies that were in
7 the -- in the Cui meta-analysis in English,
8 so to speak. Names and numbers.

9 Q Okay.

10 So out of the Cui article, you
11 relied on the abstract and the table --

12 A Sure.

13 Q -- on 728?

14 A Yeah.

15 Q And that's all you relied on,
16 because the rest of it is in Chinese, so you
17 can't read it, right?

18 A Correct.

19 Q Okay.

20 You mentioned that the hazard
21 ratio in Cui was 1.18?

22 A Right.

23 Q Where is that on this table, if you
24 can mark it?

25 (Deponent complies.)

1 A Right there. And --

2 (Deponent complies.)

3 Q Okay.

4 And the statement that you
5 have highlighted states: "The relationship
6 between NDMA and esophageal cancer was not
7 significant."

8 Correct?

9 A Not statistically significant? Is
10 that what it says? Okay, not statistically
11 significant is what he means, he/she.

12 Q You read what it says. I want to
13 make sure we get it right.

14 A "The relationship between NDMA and
15 esophageal cancer was not significant
16 (RR=1.18, 95 percent confidence interval .98
17 to 1.41)."

18 Q Just jumping around a couple of
19 things on your --

20 A We're done with this?

21 Q Yeah, we're done with that. Thank
22 you.

23 (Pause.)

24 Q Okay.

25 On paragraph 25 of your

1 report --

2 A Okay.

3 Q -- it states: "The Zhu, et al.,
4 study has the second highest top quintile
5 level of NDMA LCE amongst these studies."

6 Did you mean to say
7 "quartile"?

8 (The deponent read the
9 document.)

10 A That's a reasonable question. It's
11 a little -- I should have used some other
12 terminology. It is quintile, because there
13 are quintiles in the Zhu paper. It's divided
14 into five, you know, to an extent, blocks.

15 Some of the other ones are
16 quartiles and some of them are tertiles.

17 So the more correct -- a more
18 accurate phrasing here would be -- "has the
19 second highest top bracket of NDMA LCE
20 amongst all the studies" would have been a
21 more accurate, a -- more correct, arguably.
22 It is a quintile.

23 Q Do you want to revise it, the same
24 page where you had the earlier revision?

25 MR. NIGH: Object to form.

1 Q If it's more accurate.

2 A Sure. Quintile with bracket. I
3 hope that's not an [unintelligible].

4 Q I think your testimony explained
5 it.

6 On -- I'm going to -- I want
7 to -- let's talk about the occupational study
8 that -- page 8 of your report, evidence from
9 occupational study.

10 Hidajat was the only
11 occupational study that you considered in
12 your review.

13 A Correct.

14 Q Okay.

15 And so, again, the Hidajat was
16 one that was in Dr. Etminan's set, right?

17 A Sure.

18 Q Okay.

19 And you didn't do any
20 additional occupational study/research to
21 identify any other articles?

22 A Other than as we talked about,
23 looking at references in these papers.

24 Q Did you look at the references in
25 Hidajat?

1 A Yes.

2 Q But you didn't rely on any of those
3 references in forming your opinion in this
4 expert report?

5 A No, because none of them quantified
6 the amount of NDMA.

7 (Exhibit 26 marked for
8 identification.)

9 BY MS. LOCKARD:

10 Q And so based on the Galer paper,
11 which was Exhibit 26, you assumed a standard
12 measure that the average worker breathed a
13 certain amount per day.

14 Is that correct?

15 A Sure.

16 Q And then it looks like you also
17 assumed the air contained a certain amount of
18 the impurity?

19 MR. NIGH: Object to form.

20 A I didn't assume that. That comes
21 from Hidajat.

22 Q And in rendering your opinion,
23 though, you assumed that the exposure type
24 between inhalation and ingestion were
25 similar?

1 A Well, specifically, I assumed,
2 because Dr. Panigrahy told me that they
3 have -- they are similarly carcinogenic via
4 either route.

5 Q You have no basis for offering that
6 opinion that they are actually similar via
7 either route, right?

8 MR. NIGH: Object to form.

9 A I have a basis. My basis is what
10 Dr. Panigrahy told me, but it's outside the
11 area of my scope and my expertise.

12 Q I assume you don't know how NDMA or
13 NDEA are metabolized in the body.

14 Is that also outside of your
15 expertise?

16 A That is outside my expertise.

17 Q And in terms of any opinions about
18 how NDMA or NDEA affect different organ
19 systems, is that also outside of your
20 expertise?

21 MR. NIGH: Object to form.

22 A Yes, that's outside my area of
23 expertise.

24 Q In paragraph 34 --

25 A Okay.

1 Q -- so you state, "Per Hidajat, et
2 al., cumulative exposure to greater than
3 7,514 micrograms NDMA statistically
4 significantly increases one's risk of
5 developing the following cancers: Bladder,
6 lung, stomach, multiple myeloma, esophageal,
7 prostate and prostate."

8 So is there -- is that an
9 error? Should that not be "prostate" twice?

10 A Oh, my goodness. Ha, ha, indeed.

11 Q Okay.

12 A Yes.

13 Q What should be substituted there?

14 (The deponent read the
15 document.)

16 A Pancreas. Good catch. You can
17 read it off -- the previous page you can see
18 and read it off the table.

19 Q Will you highlight that too for me,
20 sir?

21 (Deponent complies.)

22 Q Exhibit -- I'll need to get that
23 one back from you, because that will be an
24 original.

25 Your report in paragraph 35

1 states that: "Based on valsartan dosing, the
2 levels of the NDMA reported in contaminated
3 valsartan and the time frame over which the
4 contamination occurred, it is scientifically
5 plausible that users of contaminated
6 valsartan could develop cancer."

7 My question is, what do you
8 mean by scientifically plausible?

9 A I mean -- you know, I studied
10 across a variety of dietary studies, and
11 significant occupational study, and the
12 association between certain amounts of
13 cumulative exposure to NDMA and cancer
14 outcomes, and, you know, in many cases, there
15 are statistically significant associations,
16 you know, between them.

17 And so, you know, if indeed
18 these levels of NDMA -- in these studies if
19 indeed they cause cancer, this is exactly
20 what you'd expect to see. These kinds of
21 associations are exactly what you'd expect to
22 see.

23 And based on this analysis, it
24 seems entirely plausible to me that user --
25 based on what I know about the contamination

1 levels in valsartan, it's entirely plausible
2 to me that the contaminated valsartan --
3 those folks could have developed -- the folks
4 that took contaminated valsartan could have
5 developed cancer.

6 Q But you cannot offer to any
7 reasonable degree of scientific certainty
8 that people who took that valsartan with the
9 nitrosamine impurity over the time frame you
10 assume developed cancer as a result of taking
11 valsartan?

12 MR. NIGH: Object to form.

13 A My opinion is not -- is not a
14 causal opinion. I'm not offering an opinion
15 the contaminated valsartan caused the cancer.

16 I'm -- statistical analysis is
17 entirely consistent with that proposition.

18 Q So the takeaway is that your
19 statistical analysis of the studies relied on
20 by Etminan are -- is consistent with
21 Etminan's opinion that valsartan impurity
22 caused cancer.

23 Is that right?

24 MR. NIGH: Object to form.

25 A Certainly. Yeah. It is consistent

1 with that opinion. My analysis is consistent
2 with that opinion.

3 Q And your opinion hinders on the
4 opinion of Dr. Etminan both in terms of
5 general causation and the selection of his
6 papers?

7 A No.

8 MR. NIGH: Object to form.

9 A So my -- nothing in here depends on
10 his causal -- his opinion about causation.
11 Nothing in here depends on that.

12 Q Well, it depends on the papers that
13 he told you to review, though, doesn't it?

14 MR. NIGH: Object to form.

15 A So he did a search. I took that as
16 my starting point. I took that list of
17 studies as my -- as my starting point. I
18 might have expanded it.

19 As it turned out, I didn't
20 find anything beyond that. So, yeah, in that
21 sense I'm relying on his list of studies. It
22 wasn't my starting point.

23 Q Is "scientifically plausible" a
24 term that you use or that is generally
25 accepted in your practice as a statistician?

1 A Sure. Yeah.

2 Q Do you use that in your papers?

3 A Oh, I would guess so. Now you're
4 going to ask me to point to a paper where I
5 used it, and I'm not able to do that sitting
6 here, but I imagine I have used that.

7 Q And you -- in this case, you did
8 not do a Bradford Hill analysis?

9 A No.

10 Q You weren't asked to do that?

11 A Did you know "Bradford" was his
12 middle name?

13 Q I did not know that.

14 A So strictly speaking, it should be
15 a Hill analysis, or Austin Bradford Hill
16 analysis.

17 Q That's less flashy.

18 THE DEPONENT: Did you know
19 that?

20 MR. NIGH: I've heard the name
21 referenced.

22 BY MS. LOCKARD:

23 Q So the time frame that you're
24 assuming here in paragraph 35 is -- is what?

25 You're saying based on the

1 time frame over which the contamination
2 occurred.

3 What's the time frame that
4 you're assuming in paragraph 35?

5 MR. NIGH: Object to form.

6 A I don't know. I don't have any
7 data on this topic. But as I understand it,
8 in some cases people were consuming these
9 tablets for years, these contaminated tablets
10 for years.

11 That's my understanding.

12 Q But you don't know how many
13 years --

14 A I don't. But years -- small number
15 of years is enough to get to the levels in
16 some of these studies. That is my -- I don't
17 know the exact number of years. But in my
18 report, I am offering an opinion about the --
19 it's a small -- small number of years at,
20 say, 20 milligrams, 20 micrograms a day and
21 will get you to the levels that are
22 problematic in -- in the dietary studies or
23 in Hidajat.

24 Q What would 20 micrograms of NDMA
25 daily for a year be in terms of the lifetime

1 cumulative exposure?

2 MR. NIGH: Object to form.

3 A That doesn't make any sense. You
4 said take what -- taking that much per day
5 for a year, you mean for --

6 Q The 20-microgram daily dose for a
7 year, one year, what would that be in terms
8 of the lifetime cumulative exposure?

9 Can you calculate that?

10 A Depends on the lifetime. So it's
11 20 micrograms times 365 days, times the
12 numbers of years in the lifetime, but you'll
13 have to tell me what you want to assume.

14 (Pause.)

15 Q So we talked a lot about
16 statistical significance, but what is the
17 definition of "statistically significant"?

18 A So a statistical test is --
19 produces a statistically significant result
20 from the p-values less than .05.

21 Q And do you understand the concept
22 of "relative risk" in epidemiology?

23 A I do.

24 Q If the relative risk was below 2.0,
25 would you consider that to be statistically

1 significant?

2 A You didn't give me a p-value, so
3 you --

4 Q If the paper doesn't reach a
5 95 percent confidence interval, would you
6 consider it to be statistically significant?

7 A Try again.

8 MR. NIGH: Object to form.

9 A Try again.

10 If the -- give -- can you be
11 more specific? A paper reports a relative --
12 an estimated relative risk of 2.0?

13 Q Mm-hmm.

14 A What's the confidence interval?

15 Q 95 percent.

16 A From what to what?

17 Q I don't have that factor.

18 A Well, then I can't answer the
19 question.

20 (Discussion off the record.)

21 THE VIDEOGRAPHER: The time is
22 2:35. We're off the record.

23 (Recess.)

24 THE VIDEOGRAPHER: The time is
25 2:50. We're back on the record.

1 MR. NIGH: As we're back on
2 the record, I have a couple of things. First
3 off, Dr. Madigan said something off the
4 record I think was important for him to say
5 on the record.

6 THE DEPONENT: Right.

7 So we talked about -- and I think
8 we're about to talk again, about my,
9 quote/unquote, file, and that's everything I had
10 stored that was in -- you know, on my laptop.

11 But just in case there's any
12 ambiguity, there are many other things I
13 looked at, some of which we've already
14 touched on.

15 I looked at things when I sought
16 to update the Song meta-analysis. I looked at
17 the table of the references in Dr. Etminan's
18 report. I looked at all of those. I looked at
19 the references in the studies to see were there
20 any other things that were relevant.

21 So I -- just so we're on the same
22 page, these are thing I kept, but it is
23 absolutely not the totality of what I looked at.

24 MR. NIGH: And then the second
25 thing is, I just wanted to make sure -- clear

1 that there isn't any undisclosed party that's
2 reviewing either the realtime or watching the
3 Zoom conference call.

4 If anybody is not a party, I
5 think that's -- I think that's improper given
6 our deposition protocol to be viewing the
7 realtime transcript and/or be watching the Zoom
8 conference call, you know, without being
9 disclosed.

10 MS. LOCKARD: Do we have
11 reason to think someone is doing either of
12 those?

13 MR. NIGH: I do. But as of
14 right now, I'm going to just put on if
15 anybody is not a party, I think that's
16 improper given our deposition protocol to be
17 viewing realtime transcripts or be watching
18 the Zoom conference call without being
19 disclosed.

20 MS. LOCKARD: Let's go off the
21 record for a second. Off the record, please.

22 THE VIDEOGRAPHER: The time is
23 2:52. We're off the record.

24 (Recess.)

25 THE VIDEOGRAPHER: The time is

1 2:55. We're back on the record.

2 BY MS. LOCKARD:

3 Q Okay. All right.

4 Dr. Madigan, so right before
5 we had talked about some of your materials
6 that were in your pile, and I understand your
7 testimony that you may have looked at things
8 or considered them that did not make it into
9 the file, but just for clarity's sake, if it
10 is something that you relied upon in
11 rendering your opinions, it needs to be
12 disclosed.

13 And my -- is it fair to assume
14 you have disclosed either in your report or
15 in your file anything that you relied upon?

16 A Yes, that's the intention. It's
17 just it's not everything I looked at.

18 Q Okay.

19 There are a few things in
20 there I wanted to ask you about. There's a
21 Haller, et al., Applying new competing risks
22 regression models: an overview.

23 A That's a statistical paper that is
24 referenced in Hidajat. They reference that
25 as a source for their method, so I pulled

1 that paper and looked at it.

2 Q And many of these made these
3 references in the papers you reviewed.

4 Helmut, Relevance of
5 nitrosamines to human cancer.

6 A No simple way to do this.

7 (Pause.)

8 A I don't -- I see it here. I don't
9 recall. I don't think I referenced it. If I
10 didn't reference it in the report, I'm not
11 relying on it.

12 Q The Straif paper, Exposure to high
13 concentrations of nitrosamines and cancer
14 mortality among a cohort of rubber workers.

15 A So that's an occupational study
16 that I at one point thought might be
17 relevant, but it doesn't actually quantify
18 amounts of NDMA and NDEA.

19 Q Did you talk to Dr. Etminan about
20 this paper?

21 A I didn't talk to Dr. Etminan about
22 anything. I've never spoken to him.

23 Q Okay.

24 Did you talk with
25 Dr. Panigrahy about this paper?

1 A No.

2 Q What about -- there were some
3 supplementary materials and responses on the
4 Hidajat paper, including response by Sorahan.

5 Have you reviewed those?

6 A I did look at this. It's familiar,
7 but I don't -- I'm certainly not relying on
8 it.

9 Q Was there anything there germane to
10 your review that you recall?

11 A Not that I recall.

12 Q The Mitacek Geographic distribution
13 of liver and stomach cancers in Thailand in
14 relation to estimated dietary intake of
15 nitrate, nitrite and nitrosodimethylamine.

16 A So same answer as for Straif. It's
17 a study that I thought might be germane, but
18 in fact it isn't. Doesn't quantify the
19 amount of NDMA or NDEA.

20 Q What about the Prieto, Effects on
21 4,080 rats of chronic ingestion of
22 N-nitrosodimethylamine and
23 N-nitrosodiethylamine, a detailed
24 dose-response study?

25 A So that's a famous animal study to

1 do with the effects of NDEA and NDMA on
2 cancer, so that's -- that's a paper -- excuse
3 me -- I just -- I remember reading, you know,
4 as -- by way of background early on in my
5 work in this case.

6 Q Not one of the papers you were
7 asked to review by counsel?

8 A Not that I -- not that I recall.

9 Q And nothing in there you found
10 germane to include in your report?

11 A That's correct.

12 Q Do you recall the conclusion of
13 that paper?

14 A I don't have it right in front of
15 me. You know, they -- they found a striking
16 relationship between the dose of these -- of
17 NDEA and NDMA and the occurrence of cancer in
18 rats.

19 Q Do you have any opinions about the
20 extrapolating animal study data to humans?

21 MR. NIGH: Object to form.

22 Q I mean that you intend to offer in
23 this case.

24 A There we go. No, I do not. I do
25 have opinions, but I do not intend to offer

1 opinions in this particular case on that
2 topic.

3 Q And then there's -- I think Straif
4 is in here twice.

5 What about -- there's a Dich,
6 et al., Dietary intakes of nitrite --
7 nitrate, nitrite and NDMA in the Finnish
8 Mobile Clinic Health Examination Survey.

9 Do you recall that paper?

10 A So this is -- my memory is -- I
11 believe this is correct -- that this is a
12 paper describing the same cohort as the Knekt
13 paper, which is one of the ones I do include.

14 So I think I was looking to
15 this paper for information about average age,
16 so it's the same cohort.

17 That's my memory.

18 Q Do you know if you applied any
19 average-age information that's in the Dich
20 paper?

21 A I don't think I did. I don't
22 believe I did. So I'm not relying on it.

23 Q And Tricker, et al., Carcinogenic
24 N-nitrosamines in the diet: occurrence,
25 formation, mechanisms and carcinogenic --

1 A So I think --

2 Q -- potential.

3 A Sorry. I think -- I'm not relying
4 on it. I think it's another one of these
5 papers that I looked at early on, but -- you
6 know, by way of background.

7 Q One additional item that was in
8 your file was a signature page from a
9 protective order that was entered in the
10 case.

11 A Right.

12 Q Do you recall seeing this?

13 A Yes.

14 Q We'll get that marked as an
15 exhibit.

16 MS. LOCKARD: Okay. We'll
17 mark the Acknowledgment and Agreement to be
18 Bound by Protective Order that was in your
19 file as Exhibit 22.

20 A Okay.

21 (Exhibit 22 marked for
22 identification.)

23 BY MS. LOCKARD:

24 Q Did you see anything else in the
25 stack that we haven't talked about today? I

1 know that's a terrible question.

2 A I think everything here is either
3 cited in my report or we have just talked
4 about it.

5 Q Okay.

6 A Did you have a question about the
7 Exhibit 22?

8 Q Yes. Okay. I just want to let you
9 finish what you're doing if you --

10 A I was looking for that in here,
11 actually.

12 Q Oh.

13 So do you know what this is?

14 A Yes.

15 Q What is it?

16 A It's a -- it binds me -- I signed
17 it. It binds me to hold any information that
18 I received in confidence.

19 Q Okay.

20 So you're familiar with these
21 types of protective orders from your
22 litigation work, I presume?

23 A Yes.

24 Q Okay.

25 So -- but the version that was

1 in your file is not signed. Do you know if
2 you ever signed this?

3 A I did, yeah.

4 Q Okay.

5 A This is the one that was just sent
6 to me. I presume I signed it, scanned it and
7 sent it back.

8 Q Okay.

9 In any event, you've reviewed
10 it, and you agree to be bound by the terms of
11 the protective order, right?

12 A Yes.

13 Q So what are the most -- what are
14 some of the respected professional societies
15 or professional organizations in your field?

16 A American Statistical Association,
17 Institute of Mathematical Statistics.
18 They're the two primary ones in statistics.
19 Then -- and there are more specialized
20 societies.

21 There's a society related to
22 Bayesian analysis. There's a biometrics
23 society related more to biostatistics kinds
24 of things.

25 Have I told you enough?

1 Q Are you a member of the American
2 Statistical Association?

3 A Probably.

4 Q Are you a member -- well, let me
5 ask it this way -- and we can take a look at
6 your CV as well.

7 A That wouldn't be on my CV.

8 Q You don't have your --

9 A Membership.

10 Q -- memberships --

11 Why not?

12 A I don't -- just doesn't seem very
13 interesting to put on my CV. I have
14 fellowships. I'm a fellow of a number of
15 organizations. That's an honorary thing.

16 Q But in terms of, you know,
17 membership of some professional organizations
18 like the American Statistical Association,
19 that's not something you would put on your
20 CV?

21 A No.

22 Q Okay.

23 Did you review any of the
24 defendants' expert reports?

25 A No.

1 Q So do you know who the defendants'
2 experts are?

3 A No.

4 Q Do you intend to review any of
5 their expert reports?

6 MR. NIGH: Object to form.

7 A I will if I'm asked to.

8 Q Do you have a copy of your CV?

9 A Yes, I do.

10 Q Okay.

11 So I noticed you were trained
12 at Trinity College in Dublin, correct?

13 A Right.

14 Q That's a nice place. I've been
15 there to see the Book of Kells.

16 A Good.

17 Q Were you -- were you born and
18 raised in Ireland?

19 A Yes.

20 Q When did you move to the US?

21 A 1990.

22 Q Are you a citizen of Ireland?

23 A Yes, and the US.

24 Q Dual citizenship?

25 A Yes.

1 Q Have you ever been terminated or
2 asked to leave a position?

3 A No, never.

4 Q You mentioned that you're not doing
5 any classroom teaching currently.

6 Is that right?

7 A I didn't in the last academic year.
8 I may -- I'm not going to teach a full course
9 this year. I may do some guest lectures.

10 Q What -- in the past five years or
11 so, what courses have you taught?

12 A It's on my CV.

13 Q Okay.

14 Maybe just if you could direct
15 me to --

16 A Page 36.

17 Q I see.

18 So under "Teaching" on page 36
19 at Columbia, Rutgers and University of
20 Washington --

21 A Right.

22 Q -- those were all the courses you
23 taught?

24 A Full courses, you know, where I was
25 instructor of record.

1 Are you with me? As against,
2 you know, doing a week of lectures for
3 some -- in a class. I wouldn't put that
4 here.

5 Q Understood.

6 Why are you no longer doing
7 classroom teaching?

8 A Because I'm the provost.

9 Q Just time commitment?

10 A Yeah.

11 Q So I can't help but notice, none of
12 these courses have "epidemiology" in the
13 title.

14 Is that correct?

15 A That appears to be correct, but
16 there's epidemiology in the content of many
17 of these.

18 Q Is there an epidemiology department
19 at your institution?

20 A No. Just to be clear, not at my
21 current institution. There is one at
22 Columbia.

23 Q So not at Northeastern?

24 A Correct. It's the statistics
25 department at Northeastern.

1 Q And your current title, one of
2 them, is provost at Northeastern, and the
3 other title is professor of statistics?

4 A Right.

5 Q You're not a professor of
6 epidemiology, correct?

7 A I am not.

8 Q Are you a member of any
9 professional organizations in the
10 epidemiology realm?

11 A I don't think so. I don't know
12 what I'm a member of. I don't really keep
13 track of it.

14 Q Are you -- do you have any degrees
15 in epidemiology?

16 A I do not.

17 Q Any certifications in epidemiology?

18 A I'm not entirely sure what that is,
19 but I don't -- I don't think I do.

20 Q Have you ever had any of your
21 epidemiology opinions excluded by any court?

22 A I had opinions excluded in a case
23 related to Accutane some years ago that might
24 be called epidemiology.

25 Q I think you would agree you're not

1 qualified to offer any clinical or medical
2 opinions, correct?

3 MR. NIGH: Object to form.

4 A "Clinical" is an awfully broad
5 term. I'm not a medical expert. You know,
6 does my work have clinical ramifications and
7 clinical consequences from time to time?
8 Yes.

9 Q But you don't intend to offer any
10 clinical opinions in this case --

11 MR. NIGH: Object to form.

12 Q -- outside of what's in the report?

13 A I do not. Outside of what's in my
14 report, I do not.

15 Q So you cannot -- you don't diagnose
16 or treat cancer, right?

17 A Correct.

18 Q You don't have any and won't have
19 any specific causation opinions in terms of
20 whether nitrosamines in valsartan caused any
21 particular patient's cancer?

22 A Correct.

23 Q I assume you don't have any intent
24 to offer opinions about any individual
25 plaintiffs' damages in this case?

1 A I do not.

2 Q And you're not a pathologist,
3 oncologist or hematologist, right?

4 A Correct.

5 Q And you're not a cell biology
6 expert?

7 A I am not.

8 Q You're not a toxicologist?

9 A I am not.

10 Q And you are not intending to give
11 toxicology opinions in this case, correct?

12 A Correct.

13 MR. NIGH: Object to form.

14 Q And you're not a pharmacologist or
15 a pharmacokinetics expert, correct?

16 A Correct.

17 Q And you're not qualified to offer
18 opinions about how nitrosamines are absorbed
19 in the human body? Is that true?

20 A That's true.

21 Q Now, you -- on your CV, you had
22 some involvement in FDA advisory -- in an FDA
23 advisory committee.

24 A Yes.

25 Q What was the role that you served

1 on the FDA advisory committee?

2 A I was a voting member.

3 Q Was it an advisory committee on a
4 particular issue?

5 A So it's a -- I served a term on the
6 Drug Safety and Risk Management Advisory
7 Committee. During that three-year term, you
8 know, I was involved in many, many different,
9 you know, cases that came before that
10 committee.

11 Q None of your involvement with the
12 FDA on any committee has involved
13 nitrosamines.

14 Is that right?

15 A Probably not. Not that I can
16 recall, and probably not.

17 Q In connection with your roles with
18 FDA, none of those involved valsartan either.

19 Is that right?

20 A Probably not. It's a matter of
21 public record what came before that
22 committee. I don't remember anything to do
23 with valsartan.

24 Q You've never been employed at the
25 FDA, have you?

1 A Not really. Strictly speaking, I
2 was something called an SGE, a special
3 government employee. So when you're on one
4 of these committees, you're actually
5 technically an employee, but not -- not in
6 any normal sense of the word.

7 Q Okay.

8 So I assume you're not
9 planning to offer any opinion about CGMPs or
10 quality systems?

11 A I am not.

12 Q And no opinions about the labeling
13 of the valsartan? Adequacy of the labeling,
14 for example?

15 A I do not intend to offer such
16 opinions.

17 Q And you haven't reviewed any
18 labeling for valsartan, have you?

19 A I have not.

20 Q And you're not offering any
21 opinions about regulatory compliance or FDA
22 rules and regulations, correct?

23 A In this case, no, I'm not.

24 (Pause.)

25 Q And just to be sure, you don't

1 intend to offer any opinions about liability
2 in this case in terms of what the
3 manufacturers or other defendants did or
4 should have done?

5 MR. NIGH: Object to form.

6 A I don't believe so.

7 Q You won't come testify about
8 standard of care applicable to manufacturers,
9 right?

10 MR. NIGH: Object to form.

11 A I don't think so.

12 Q Let me show you what I've marked as
13 Exhibit 23 and 24. I'll get you a copy here.

14 (Exhibit 23 marked for
15 identification.)

16 (Exhibit 24 marked for
17 identification.)

18 BY MS. LOCKARD:

19 Q Do you recognize either of these
20 documents?

21 A Sure.

22 Q What are they?

23 A One is a paper that was published
24 in The American Statistician, which is a
25 publication of the American Statistical

1 Association, and the other looks like a press
2 release related to the same thing.

3 Q Do you get any publications or
4 guidelines from the ASA, email or in the
5 mail?

6 A No.

7 Q Do you know if you would have
8 received the press release?

9 A I really don't know.

10 Q Okay.

11 So 23 is the ASA news, and
12 it's entitled "American Statistical
13 Association Releases Statement on Statistical
14 Significance of p-values."

15 And Exhibit 24 is, "The ASA
16 Statement on p-Values: Context, Process and
17 Purpose."

18 And you -- have you read the
19 statement in its entirety?

20 A Yes. Not recently. It's not fresh
21 in my mind, but...

22 Q Do you know Dr. Wasserstein and
23 Dr. Lazar?

24 A Lazar, I do.

25 Q Were you invited to comment on this

1 article or this guideline, rather?

2 A I don't know. I don't remember. I
3 didn't -- you asked was I invited. It's
4 possible. I don't remember.

5 Q So --

6 (Pause.)

7 Q So if you turn to, I guess,
8 page 131 at the top?

9 A Yes.

10 Q And it says: "ASA Statement on
11 Statistical Significance and P-values," and
12 there's the introduction.

13 Are you with me?

14 A Yes.

15 Q Do you agree with what's in this
16 guideline?

17 A I can't -- I -- I haven't looked at
18 this in probably five years. I can't go
19 there unless you give me -- I can read it,
20 but...

21 Q Let me just -- so I'll pull out a
22 few things.

23 In the introduction on the
24 second paragraph --

25 A Okay.

1 Q -- the second line, it says:

2 "While the p-value can be a useful
3 statistical measure, it is commonly misused
4 and misinterpreted."

5 Do you agree with that
6 statement?

7 A Yeah, that's not unreasonable. I
8 don't misuse it or misinterpret it, I should
9 add, but is it, you know, is it misused and
10 misinterpreted sometimes? Yeah.

11 Q And it says: "What is a p-Value?"
12 on point 2. And this paper says:
13 "Informally, a p-value is the probability
14 under a specified statistical model that a
15 statistical summary of the data (for example,
16 the sample mean difference between two
17 compared groups) would be equal to or more
18 extreme than its observed value."

19 So is that a reasonable
20 definition of the p-value?

21 A Yeah, it is informal. It's not
22 mathematically precise, but it's not
23 unreasonable.

24 Q Okay.

25 And under Principles, it says,

1 the first one: "P-values can indicate how
2 incompatible the data are with a specified
3 statistical model."

4 Do you agree with that?

5 A Yeah.

6 Q No. 2, the second principle is:
7 "P-values do not measure the probability that
8 the studied hypothesis is true or the
9 probability that the data were produced by
10 random chance alone."

11 Do you agree with that?

12 A That's very ambiguous. P-values do
13 not measure the probability that the studied
14 hypothesis is true. I don't -- "studied
15 hypothesis" is kind of an ambiguous term
16 there.

17 If you mean -- if by that they
18 mean a null hypothesis -- actually, I think
19 they do. If you interpret that to mean the
20 null hypothesis, then I certainly agree.

21 The probability that the data
22 were produced by random chance alone, I don't
23 exactly know what that means, but that's not
24 what a p-value is.

25 Q Principle No. 3 says: "Scientific

1 conclusions in business or policy decisions
2 should not be based only on whether a p-value
3 passes a specific threshold."

4 Do you agree with that?

5 A I do.

6 Q No. 4 principle states: "Proper
7 inference requires full reporting and
8 transparency."

9 Do you agree with that?

10 A Who could disagree with it? But I
11 don't know what it means exactly.

12 Q Seems vague, I guess.

13 All right. No. 4 --

14 A 5.

15 Q Excuse me. Start over.

16 Principle No. 5: "A p-value
17 or statistical significance does not measure
18 the size of an effect or the importance of a
19 result."

20 Do you agree with that?

21 A I do.

22 Q No. 6: "By itself, a P-value does
23 not provide a good measure of evidence
24 regarding a model or a hypothesis."

25 Do you agree with that?

1 A What I'm stumbling over there is
2 "good." What does that mean? It is what it
3 is. It measures -- it's a measure of the
4 strength of the evidence against the null
5 hypothesis in a particular sense, so it's
6 a -- it's kind of too vague for me to just
7 give you a blanket "yes, I agree," or "no, I
8 don't."

9 Q Okay.

10 And then the final statement
11 in the conclusion: "No single index should
12 substitute for scientific reasoning."

13 A It's motherhood and apple pie,
14 sure.

15 Q Everybody would agree with that,
16 right?

17 A You couldn't disagree with it. I
18 don't know what it means exactly.

19 Q But the point is, nobody would
20 disagree that no single index should
21 substitute for scientific reasoning, right?

22 A Sure. I don't know what an index
23 is, but yeah.

24 Q Does -- does your university know
25 that you're serving as an expert witness in

1 this case?

2 A Yes.

3 Q Do you have to report that at
4 Northeastern?

5 A I'm supposed to disclose outside
6 activities, which I do all the time.

7 Q Do they provide any input into what
8 you can review or not?

9 A No, absolutely not.

10 Q Do they do any peer review of your
11 expert reports?

12 A No.

13 Q Has anybody at the university ever
14 asked to approve any of your opinions in an
15 expert report?

16 A No. They published an article
17 about my work. Just saying.

18 Q The university did?

19 A Yes.

20 Q Based on an expert report?

21 A No, no, no, no, no, just in
22 general, in the kind of university magazine.

23 Q I think you -- when I asked you
24 about any exclusions of your testimony, you
25 said you recalled a court order excluding

1 some testimony in the Accutane litigation?

2 A You asked a narrower question, but
3 yes.

4 Q And the Accutane litigation was --
5 that was a judge in New Jersey state court?

6 A I can't remember what court it was.
7 It was in -- physically in New Jersey, that
8 is true.

9 Q So at least one judge in New Jersey
10 excluded your opinions on general causation.

11 Is that right?

12 A No, no. He excluded specific
13 opinions related to analysis I had done. I
14 don't -- my memory is it was nothing to do
15 with general causation.

16 Q Did you read the judge's opinion?

17 A Sure did.

18 Q Did you agree with it?

19 A No. But I did agree wholeheartedly
20 with the appellate court who overturned the
21 judge's ruling and who said things like --
22 that my opinions weren't consistent and --
23 I'd be happy to read you --

24 Q That's okay. We have a full file.
25 Got a lot of paper.

1 And did you have some of your
2 testimony excluded in the Vioxx litigation?

3 A Not that I can recall. Maybe I --

4 MR. NIGH: Object to form.

5 A Maybe -- in some litigation, maybe
6 twice or three times, medical opinions were
7 excluded, which I contend I was not offering
8 in the first place.

9 Maybe that's what happened in
10 Vioxx, but I don't remember.

11 Q All right.

12 And do you recall having your
13 opinion excluded in the Abilify litigation?

14 MR. NIGH: Object to form.

15 A No. So it was limited. So again,
16 again, it was -- my memory of that one was
17 that it was to do with the judge felt that
18 I -- something I said was a medical opinion.

19 I was told I cannot offer
20 medical opinions.

21 Q The judge said you cannot offer
22 medical or scientific causation opinions in
23 Abilify.

24 Isn't that right?

25 MR. NIGH: Object to form.

1 A I don't remember that. Maybe
2 you've got it in front of you, but that's
3 fine.

4 Q This is the order I have. We can
5 get it marked as Exhibit No. 2- -- 24 [sic].

6 (Exhibit 25 marked for
7 identification.)

8 BY MS. LOCKARD:

9 Q And I'll just give you a moment to
10 look at that.

11 MR. NIGH: You don't have an
12 extra copy of this one either?

13 MS. LOCKARD: I don't think
14 this is the same. It's not. I don't have an
15 extra copy.

16 Do you have access to the -- he's
17 going to load it up on the -- on the Zoom if you
18 have access to the exhibits that way. Abilify.

19 A I can't look at a document this
20 large in realtime. What do you want to do
21 here? And it's 150 pages. I don't remember.

22 Q Okay. I'll take it back.

23 A Okay.

24 Q I'll just ask questions about it.

25 (Pause.)

1 Q Okay.

2 MS. LOCKARD: Correction, the
3 exhibit is No. 25.

4 (Pause.)

5 BY MS. LOCKARD:

6 Q Do you recall your testimony being
7 excluded earlier this year in the Incretin
8 litigation?

9 A I do.

10 Q What was --

11 A This year or last year?

12 Q I have an order looking like
13 March 9, 2021.

14 A Okay.

15 Q Does that sound right?

16 A No, but maybe. I could be wrong
17 about that.

18 Q Do you recall the basis for
19 excluding your testimony in that litigation?

20 A I do.

21 Q What was it?

22 A Two things: One, the lawyers that
23 I had worked with filed a report that I wrote
24 in 2015 unbeknownst to me, and the judge
25 excluded it because there are new data.

1 Indeed, there are.

2 And then the second one was I
3 did a more recent report that was much
4 narrower, and the claim was I used a
5 different methodology that I had used in
6 2015, which is correct, but for -- for very
7 good, solid, scientific reasons, the judge
8 didn't read or didn't understand.

9 Q So you disagree with that
10 exclusion, I assume?

11 A Yes.

12 MR. NIGH: Object to form.

13 A Well, yes and no, actually. The
14 exclusion of the 2015 report I don't
15 necessarily disagree with.

16 MR. NIGH: Object to form.

17 (Counsel conferred.)

18 BY MS. LOCKARD:

19 Q So Exhibit 25 on page 150, that's
20 Judge Casey Rodgers' order.

21 A Are you going to give it back to
22 me?

23 Q Yes, I'm going to --

24 A Okay, okay.

25 Q All right.

1 The order that I'm reading
2 from, to refresh your recollection,
3 Dr. Madigan, is the court's summary
4 conclusion on the motion to exclude the
5 general causation opinion of David Madigan is
6 that it was due to be granted in part and
7 denied in part.

8 The court went on to say:
9 "Dr. Madigan may not offer an expert opinion
10 on medical causation and also may not testify
11 about the five statistically insignificant
12 p-values he calculated from the clinical
13 trial data." And then, "In all other
14 respects, his opinion is admissible as to
15 statistics."

16 MR. NIGH: Objection.

17 A Okay.

18 Q So does that refresh your
19 recollection as to the exclusion by the court
20 in that litigation?

21 A Yes. So she excluded me from
22 offering medical opinions, and then there
23 were five specific p-values that for some
24 reason she knew more about than I did and
25 decided it shouldn't -- shouldn't be allowed.

1 Q Okay.

2 So there have been, I believe,
3 two Abilify orders, the Accutane order, the
4 Incretin order. So that's four that we've
5 discussed that involved the limiting or
6 excluding some or all of your deposition
7 testimony?

8 MR. NIGH: Object to form.

9 Q Is that right? At least four?

10 A You just -- yeah, sure. You
11 mentioned four particular cases where I -- in
12 two cases my opinion was excluded; in two
13 cases my opinion was -- was narrowed.
14 Although I would -- in the Abilify context,
15 it's in a completely insignificant way.

16 What was the fourth one,
17 actually? Vioxx?

18 Q There were two Abilify orders.

19 A Oh, sorry, two Abilify orders.

20 Q And are you -- do you recall any
21 other orders from any other judge either
22 excluding or limiting your opinions?

23 A There are no others where my
24 opinions are excluded. Limited, I can't be
25 sure. As I say, I have this memory from time

1 to time of being told I can't offer medical
2 opinions, and I don't.

3 MR. NIGH: Objection.

4 A I agree. I shouldn't offer medical
5 opinions, and I don't.

6 Q Okay.

7 Have you ever been convicted
8 of a crime?

9 A Is this Alice's Restaurant?

10 No.

11 Q Surely you've been asked that
12 before in a deposition. I can't be the
13 first.

14 (Laughter.)

15 Q Have you ever filed for bankruptcy?

16 A No.

17 Q Do you -- have you told me all the
18 opinions you hold today as they relate to
19 this case?

20 MR. NIGH: Object to form.

21 A No, I have not. We've -- they're
22 contained in the -- in the report that I
23 have, but I -- we haven't talked about every
24 last little thing in there, I don't think.

25 Q Okay. Understood.

1 But in terms of what's in your
2 report, is there anything in addition that
3 you need to add, supplement or change in
4 order to complete your opinions in this case?

5 A Not that I'm aware of. Actually, I
6 suppose other than the correction that we
7 went over this morning.

8 Q Okay.

9 Other than the corrected
10 version as it stands today after today's
11 testimony, is there anything else you need to
12 do to change or supplement your report to
13 make it complete?

14 A I don't believe so.

15 MR. NIGH: Object to form.

16 (Pause.)

17 BY MS. LOCKARD:

18 Q My computer keeps freezing on me.
19 I think it's telling me it's time to stop.

20 I'm going to stop here and
21 turn the questioning over to Mr. Trischler or
22 anybody else who has questions. I may have
23 some additional wrap-up questions once I can
24 get my computer fixed.

25 MR. TRISCHLER: Okay. We'll

1 go off the record.

2 THE VIDEOGRAPHER: The time is

3 3:43. We're off the record.

4 (Recess.)

5 THE VIDEOGRAPHER: The time is

6 3:48. We're back on the record.

7

8 EXAMINATION

9 BY MR. TRISCHLER:

10 Q Dr. Madigan, good afternoon.

11 A Hello.

12 Q I introduced myself to you at the
13 beginning of our session today. My name is
14 Clem Trischler. I'm one of the lawyers
15 representing some of the defendants in the
16 valsartan litigation, particularly Mylan
17 Pharmaceuticals.

18 Okay?

19 A Okay.

20 Q I'm going to ask you a few
21 questions. I'm going to try not to be
22 repetitive. Ms. Lockard was very -- very
23 thorough in her examination, so there's just
24 a few areas that I'd really like to cover
25 with you.

1 And I guess I'll start when
2 you were retained in this case. I understand
3 from looking at some of your invoices that
4 were previously marked as exhibits that you
5 were retained sometime around March of 2020
6 to provide consulting litigation services for
7 the plaintiffs in the valsartan litigation,
8 correct?

9 A Yes.

10 Q And you were contacted by Mr. Nigh
11 or members of his firm, I believe you told
12 us?

13 A Right. Yes.

14 Q And I guess my question was, you
15 were contacted by the plaintiffs' lawyers to
16 work in this case. You did not seek them
17 out.

18 Fair to say?

19 A Correct.

20 Q And prior to the time you were
21 contacted by the plaintiffs' lawyers in this
22 case, have you ever participated in any
23 epidemiological studies regarding the
24 carcinogenic effects of NDMA?

25 A No.

1 Q Prior to the time you were
2 contacted by the plaintiffs' lawyers in this
3 case, did you ever participate in any
4 epidemiological studies regarding
5 carcinogenic effects of NDEA in humans?

6 A No.

7 Q Had you ever -- before you were
8 contacted to serve as an expert witness in
9 this case, had you ever published any papers
10 relating to NDMA or NDEA?

11 A No.

12 Q So before Mr. Nigh knocked on your
13 door, had you ever done a statistical
14 analysis to evaluate the strength of
15 association, dose response or increased risk
16 of cancer from exposure to NDEA?

17 A No, I had not.

18 Q Before you were contacted to do
19 this work in a litigation context, had you
20 ever done a statistical analysis to evaluate
21 the strength of association, dose response or
22 increased risk of cancer from exposure to
23 NDEA?

24 A No.

25 Q You were kind enough to provide us

1 with your CV, and I think, if I recall
2 correctly, your CV suggests that you
3 published at least 180 technical papers
4 during the course of your career on issues
5 relating to biostatistics and epidemiology.

6 Is that fair to say?

7 MR. NIGH: Object to form.

8 A Sure.

9 Q How many of those 180 papers relate
10 to NDEA?

11 A Zero, as far as I know.

12 Q How many --

13 A Is that the same question I
14 answered a minute ago or am I missing
15 something?

16 Q Might be. It's certainly similar.
17 I don't know if it's the same.

18 How many of those 180 papers
19 relate to NDMA?

20 A Zero.

21 Q One of the things that we talked
22 about earlier today was in your report you
23 make reference to the Johnson study.

24 Do you recall talking about
25 that?

1 A I do.

2 Q I think it's on page 2 of your
3 report where that reference appears under the
4 Introduction section.

5 Is that right?

6 A Right.

7 Q And I think that Johnson paper is
8 entitled "Permitted Daily Exposure Limits for
9 Nitrosamines."

10 Do I have that right?

11 A Yes.

12 Q And you -- in your report, you do
13 not offer any criticisms of the Johnson
14 paper, correct?

15 A I mean, not -- not directly, but my
16 table has, you know, statistically
17 significant increased risks at much lower
18 doses than in Johnson, so implicitly there's
19 a criticism of Johnson.

20 Q Do you state any criticisms of
21 Johnson's report in -- of Johnson's paper in
22 your report?

23 A No, I do not.

24 MR. NIGH: Objection.

25 Q Do you take any issue with his

1 methodology anywhere in your report?

2 A It's outside of scope of my
3 expertise. So let me answer your question.
4 No, I do not. It's outside the scope of my
5 expertise. I wouldn't.

6 Q And do you take -- do you -- in
7 your report that you wrote in this case, did
8 you dispute any of the conclusions that
9 Johnson and his colleagues reached in their
10 paper?

11 MR. NIGH: Object to form.

12 A No. Nor would I. It's outside the
13 scope of my expertise.

14 Q In fact, in the report all you did
15 was to cite to the conclusions that Johnson
16 and his colleagues reached regarding safe
17 exposure levels to both NDEA and NDMA,
18 correct?

19 MR. NIGH: Object to form.

20 A I think I'm agreeing with you. I
21 just noted I had seen that. I just noted it
22 here. I don't agree with it in the sense
23 that I told you.

24 There are statistically
25 significant increased risks at much lower

1 doses in what I looked at.

2 Q Based on your review of other
3 papers that were provided to you by one of
4 the plaintiffs' experts --

5 MR. NIGH: Object to form.

6 Q -- right?

7 A No. So Dr. Etminan didn't provide
8 me with the papers. I started with a list of
9 papers that were pursuant to a search that he
10 did.

11 So I'm just taking issue
12 with -- the way you phrased it was he
13 provide -- he didn't provide me the papers.

14 Q He provided you with the list of
15 papers to --

16 A Yes, that I started with.

17 Q Started with. Understood. Thank
18 you.

19 But what you actually write in
20 your report as it relates to the Johnson
21 study is that that study suggests that NDMA
22 levels as high as 6.2 micrograms per day
23 could be safe, correct?

24 MR. NIGH: Objection.

25 A No. I said more recently they have

1 suggested -- somebody else has suggested
2 that. I'm not -- I'm -- you know, I -- I
3 am --

4 It's outside my expertise
5 to -- to provide a critique, you know, of
6 that paper. What I can do is contrast with
7 the analysis I did.

8 Q Well, I'm just trying to -- do
9 these words appear in your report: Johnson,
10 et al. -- "Johnson, et al., have suggested
11 that NDMA levels as high as 6.2 micrograms
12 per day could be safe."

13 Indeed, that was just -- it's
14 a direct quote from their paper. And if
15 we --

16 A It's not a direct quote, but
17 it's -- you know, it's implicit -- it's a
18 fact that's lifted from their paper.

19 Q Okay.

20 And 6.2 micrograms per day is
21 roughly 6,200 nanograms per day, correct?

22 A Precisely, yeah.

23 Q And you also note in your report
24 that Johnson has suggested that NDEA levels
25 as high as 2.2 micrograms per day could be

1 safe, correct?

2 A That's what he -- that's what's in
3 that paper, yes.

4 Q Which translates to 2,200 nanograms
5 per day?

6 A Right.

7 Q And based on -- although you had
8 never done any research of NDEA or NDMA prior
9 to coming to this case, have you learned
10 since that time that nitrosamines are
11 ubiquitous?

12 MR. NIGH: Object to form.

13 A No.

14 Q Do you know -- do you agree based
15 on the research that you've done and the
16 papers that you've read that we're all
17 exposed to nitrosamines on a daily basis?

18 A Not something I looked at.

19 Q That's news to you?

20 MR. NIGH: Object to form.

21 A I looked at NDMA and NDEA, and I
22 learned that there are certain levels of
23 those substances in foods, so that's what I
24 learned.

25 Q Okay.

1 So you looked at -- you looked
2 at papers from a list given to you by one of
3 the plaintiffs' experts that suggested that
4 there was NDEA and NDMA in certain dietary
5 substances, correct?

6 MR. NIGH: Object to form.

7 A Sure. You're phrasing it in a
8 very, you know -- he did a search. He
9 searched databases, and I'm -- with certain
10 search criteria and produced a list of
11 papers.

12 I used that as my starting
13 point.

14 Q Well you said -- in fairness, I
15 think you said you never spoke to Etminan,
16 right?

17 A Right.

18 Q So you don't know what he did to
19 generate the list --

20 A No, I was told he did a search.

21 Q By whom?

22 A Counsel. So counsel told me what
23 the search was that he did.

24 Q From reviewing the papers that
25 discussed NDEA and NDMA levels in dietary

1 substances, have you come to learn that we
2 are all exposed to those two nitrosamines on
3 a daily basis?

4 A No, I don't know. I've learnt that
5 there's NDMA and NDEA in certain foods. So
6 therefore, if you consume those foods, I
7 guess you will ingest some NDEA.

8 I have no idea how ubiquitous
9 that is. I don't know.

10 Q From the literature that you've
11 read, do you have an opinion as to whether
12 there are certain exposure levels of -- to
13 NDMA that presents a de minimis risk of harm
14 to human beings?

15 MR. NIGH: Object to form.

16 A That's not something I know
17 anything about.

18 Q From the research that you've done
19 in this case, do you have an opinion as to
20 whether there are certain exposure levels of
21 NDEA that are so low as to prevent a
22 de minimis risk of harm to humans?

23 MR. NIGH: Object to form.

24 A So I don't know. It's not
25 something I've looked at. I quoted what the

1 FDA said. I quoted Johnson. I don't know.

2 That's not something I studied myself.

3 Q Fair enough.

4 One of the papers that you did
5 talk about in your report that I wanted to
6 ask you a little bit about was the Zheng
7 paper, which is spelled Z-H-E-N-G for the
8 benefit of our court reporter. Okay?

9 And I think that paper might
10 be marked as Exhibit 20 to the deposition for
11 purposes of our record.

12 A Okay.

13 Q You want to grab that and have it
14 in front of you.

15 A I'm there.

16 Q And this would have -- Zheng would
17 have been one of the papers that would have
18 been on the list provided to you from
19 Etminan, correct?

20 A Correct.

21 Q And since it's on your list and
22 discussed in your report, you obviously would
23 have read it, correct?

24 A Yes.

25 Q And if we go to page 255 of the --

1 A Yup.

2 Q -- paper, which is the second page
3 of our exhibit, Zheng and his colleagues
4 acknowledge that there are epidemiological
5 studies investigating the association of
6 dietary nitroso compounds with pancreatic
7 cancer that are inconsistent, correct?

8 A Where are you?

9 Q Oh, I'm sorry, go -- if I can
10 point? This paragraph, okay?

11 Paragraph on left-hand column
12 starting with "Although the carcinogenicity
13 of processed meat is under significant
14 attention."

15 Are you with me?

16 A Yes.

17 Q Isn't it true that what Zheng and
18 his colleagues write there is that
19 epidemiological studies investigating the
20 association of dietary nitroso compounds with
21 pancreatic cancer are inconsistent?

22 MR. NIGH: Object to form.

23 A It's more specific than that.
24 So -- actually, what was the question? Did
25 you read it correctly? Can I have a

1 question?

2 Q Yes.

3 A Yeah, you did.

4 Q Okay.

5 And, in fact, they go on --

6 Zheng goes on to state that there have been
7 studies suggesting that they found no
8 association between dietary intake of
9 nitrosamines and pancreatic cancer, correct?

10 A I don't see -- that's actually kind
11 of --

12 Q Sure. Let me see if I can find it
13 for you.

14 About halfway through that
15 paragraph, Zheng writes: "Among three case
16 control studies, two reported inverse
17 associations for nitrate, one reported a
18 positive association for nitrate" --

19 A 'trite.

20 Q Nitrite, thank you.

21 -- "and one reported null
22 associations for nitrate and nitrite."

23 Correct?

24 A You read that correctly.

25 Q And then in the same paper, Zheng

1 and his colleague go on to reference four
2 cohort studies that found no statistically
3 significant associations for the intake of
4 nitrates, nitrites and pancreatic cancer
5 risk, true?

6 A You read it correctly.

7 Q And I think you said that in
8 addition to just reading the Zheng paper, you
9 would have gone on and read the references to
10 this paper, correct?

11 A To see if they were -- if they
12 quantified NDMA -- not nitrates or nitrites,
13 but NDMA and/or NDEA, whether they quantified
14 it and quantified the effect sizes.

15 Q So your testimony under oath is you
16 would have read the Risch, R-I-S-C-H, paper
17 cited by Zheng?

18 A Yes, I would have looked at it for
19 sure.

20 Q You would have read the Baghurst,
21 B-A-G-H-U-R-S-T, study cited by Zheng,
22 footnote 10?

23 A Yeah, I looked at all these papers.

24 Q You would have read the papers that
25 are cited at footnotes 14 and 17 of the Zheng

1 paper?

2 A Yes.

3 Q And if we go to the conclusion,
4 what Zheng and his colleagues wrote, and I
5 think we find that conclusion beginning on
6 page 260, going on to page 261, what they
7 concluded was that there is a biologically
8 plausible association between NDEA and NDMA
9 with pancreatic cancer, correct?

10 A No, you didn't read it completely.
11 But, in summary, in this large hospital-based
12 matched case control study, we found a
13 biologically plausible cause and association
14 of two potent dietary carcinogens, NDEA and
15 NDMA, with pancreatic cancer.

16 Q And this was the only paper that
17 you cite in your entire report that dealt
18 with NDEA, true?

19 A It was the only one I found.

20 Q And the only paper that you cite
21 relating to NDEA that Zheng went on to
22 observe was that a possibility of an
23 association between NDEA and pancreatic
24 cancer needed to be confirmed in a readily
25 large -- available large prospective cohort

1 study, correct?

2 MR. NIGH: Object to form.

3 A Can you point me?

4 Q Yes, page 261.

5 (The deponent read the
6 document.)

7 A Sure, yeah.

8 Q So basically -- and the only study
9 that you cite that relates to NDEA, what the
10 authors of that study indicated was that the
11 potential association between NDEA and
12 pancreatic cancer is something that needed
13 further research, correct?

14 A Their opinion is these findings
15 need to be confirmed, but the rest of it is
16 kind of weird. And readily available. What
17 the heck's that got to do with anything?

18 Large prospective cohort
19 studies with consideration of sufficient
20 time -- I don't fully understand the rest of
21 it, but I -- they're saying it would be nice
22 if -- to get this confirmed, yeah.

23 Q My question was, the authors of the
24 Zheng paper concluded that any conclusion
25 about the association between NDEA and

1 pancreatic cancer required further research,
2 correct?

3 MR. NIGH: Object to form.

4 A Sure. You know, it's an
5 observational study with all the limitations
6 that go with that, and they're saying we'd
7 like more of them. Sure.

8 Q And they suggested that there would
9 be -- that further research, including a
10 large cohort study, before any confirmation
11 could be made, correct?

12 A That's not quite the way they
13 worded it, but it's not far off. So
14 they're -- these findings need to be
15 confirmed, sure.

16 Q And they also acknowledge that
17 there was contradictory research regarding
18 the association between NDEA and pancreatic
19 cancer, right?

20 A No, they didn't.

21 MR. NIGH: Objection.

22 A That part that you read earlier was
23 about nitrites and nitrates. Nitrites and
24 nitrates. Not NDEA specifically.

25 Q The Zheng paper does not address an

1 association between NDEA and any other form
2 of cancer, correct?

3 A That is true, right. It's -- the
4 paper is about pancreatic cancer.

5 Q And when we talk about NDEA, you
6 don't cite any observational study anywhere
7 in your report linking NDEA exposure to any
8 form of cancer other than pancreatic cancer,
9 correct?

10 A That's correct. I'm not aware of
11 such studies.

12 Q In your work in this case, did you
13 read any studies finding a statistically
14 significant increased risk of bladder cancer
15 and NDEA?

16 A And NDEA, no, I did not.

17 Q In connection with your work in
18 this case, did you read any studies finding a
19 statistically significant increased risk of
20 blood cancer and NDEA?

21 A I did not.

22 Q In connection with your work in
23 this case, did you find any studies that
24 suggest that -- a statically significant
25 increased risk of breast cancer and NDEA?

1 A I did not.

2 Q In connection with your work in
3 this case, did you find any studies that
4 suggest a statistically significant increased
5 risk of colorectal or intestinal cancer and
6 NDEA?

7 A I did not.

8 Q In connection with your work in
9 this case, did you read any studies or find
10 any studies suggesting a statistically
11 significant increased risk of gastric cancer
12 and NDEA?

13 A I did not.

14 Q In connection with your work in
15 this case, did you find any studies
16 suggesting a statistically significant
17 increased risk of kidney cancer and NDEA?

18 A I did not.

19 Q In connection with your work in
20 this case, did you find any study suggesting
21 a statistically significant increased risk of
22 liver cancer and NDEA?

23 A I did not.

24 Q In connection with your work in
25 this case, did you find any studies

1 suggesting a statistically significant risk
2 of lung cancer and NDEA?

3 A I did not.

4 Q In connection with your work in
5 this case, did you find any studies
6 suggesting a statistically significant risk
7 of -- I'm going to butcher the
8 pronunciation -- pharyngeal cancer and NDEA?

9 A I did not.

10 Q In connection with your work in
11 this case, did you find any studies
12 suggesting a statistically significant risk
13 of prostate cancer and NDEA?

14 A I did not.

15 Q In connection with your work in
16 this case, did you find any study suggesting
17 a statistically significant increased risk of
18 uterine cancer and NDEA?

19 A I did not.

20 Q Based on the absence of any
21 observation studies relating to NDEA and any
22 form of cancer other than pancreatic, I take
23 it that you are not able to testify to any
24 reasonable degree of scientific certainty
25 that exposure to NDA creates statistically

1 significant risk of developing any form of
2 cancer other than pancreatic?

3 A NDEA. I think you said "NDA."
4 That's right. I don't have -- I don't have
5 studies that are germane to that question so
6 I can't answer the question.

7 Q And just NDEA is what I was asking
8 about.

9 A You said NDA.

10 Q Not NDA, so thank you for
11 clarifying that.

12 On page 6 of your report,
13 there it is, it's numbered paragraph 26.

14 A Right.

15 Q You sort of wrote in summary
16 fashion on the subject that you and I have
17 just been talking about.

18 Your paragraph 26 reads:
19 "Concerning NDEA, Zheng, et al., shows a
20 statistically significant increased risk and
21 an LCE of 2,520 micrograms," correct?

22 A Correct.

23 Q And "LCE" is an abbreviation for
24 "lifetime cumulative exposure."

25 Is that right?

1 A Right.

2 Q And so what you write in your
3 report that you filed with the court in this
4 case -- which has been filed with the court
5 in this case is that there is a -- in your
6 opinion, a statistically significant
7 increased risk of pancreatic cancer where the
8 lifetime cumulative exposure of the NDEA is
9 greater than 2,520 micrograms?

10 A Right.

11 Q In doing the math, that would be
12 2,250,000 nanograms?

13 A Two and a half million nanograms,
14 yes.

15 Q Yes, 2,520,000 nanograms.

16 I told you at the outset I
17 represent Mylan. I don't think you've
18 reviewed any Mylan company documents in
19 connection with your work in this case.

20 Is that true?

21 A I believe that's true.

22 Q In your report, I didn't see any
23 reference to any Mylan company documents.

24 Can we agree on that?

25 A I believe that's correct. I

1 believe the only company documents are the
2 few that I referenced on page 2, and they
3 don't -- they're not from Mylan.

4 Q Right.

5 And Ms. Lockard walked you
6 through those ones you reference on page 2, I
7 think some from ZHP and some from Torrent,
8 correct?

9 A That's my memory.

10 Q And so my question to you, sir, is
11 this: Do you have any information to suggest
12 that the levels of nitrosamines in Mylan's
13 Valsartan-containing medication over the
14 period of potential exposure exceeded the LCE
15 you calculated from the Zheng paper?

16 MR. NIGH: Object to form.

17 A I have no idea. I have no such
18 opinion.

19 Q Do you have any idea or any opinion
20 that any defendants' Valsartan-containing
21 medication exceeded the LCE that you've
22 calculated for NDEA in paragraph 26 of your
23 report?

24 MR. NIGH: Objection. Form.

25 A From NDEA?

1 Q Yes, sir.

2 A I didn't -- one could do such
3 calculations. I didn't do such calculations.
4 I did them for NDMA.

5 Q And can you -- look for a moment
6 with me at your -- what you wrote in your
7 numbered paragraph 35 of your report, sir.

8 A Okay.

9 Q And essentially, the way I read
10 paragraph 35 of your report is that you
11 conclude that it's scientifically plausible
12 that certain users could have developed
13 certain cancers based on the NDMA levels in
14 the Valsartan-containing medications of some
15 of the defendants.

16 Is that essentially the
17 conclusion that you drew there?

18 A Sure, sure.

19 Q There's nothing in paragraph 35 of
20 your report that states anything with respect
21 to NDEA, agreed?

22 A There's not.

23 Q And you've already told me that
24 you've not looked at any data relating to
25 Mylan's NDEA levels in any of Mylan's

1 products, correct?

2 A You know, firstly, the reference in
3 my report to the FDA website, I do not know
4 if there's Mylan drug -- there's, you know, a
5 list. We looked at it this morning. It's an
6 exhibit.

7 Q Right.

8 A I don't know if Mylan is on that.
9 It's not something I focused on.

10 Q And that's fair. And I don't think
11 that is inconsistent with your prior
12 testimony, because I think before I had asked
13 you if you saw the Mylan company documents.

14 And so I think what you're
15 talking about now is there was information
16 about nitrosamine levels observed -- that
17 were reported by the FDA and publicly
18 available materials?

19 A Yes, yes.

20 Q And I think there may be some
21 information about Mylan levels in there.

22 A In which case it would be -- it
23 would be trivial to take those numbers and do
24 the kinds of calculations I did in my report.

25 Q Okay.

1 But you've not done the
2 calculations thus far?

3 A I have not.

4 Q And you do not intend to offer the
5 opinion that Mylan's -- that levels of NDEA
6 in Mylan's Valsartan-containing medication
7 over the period of potential exposure
8 exceeded the LCE of 2,520,000 nanograms, do
9 you?

10 MR. NIGH: Object to form.

11 A That's sort of a tricky question
12 because, like, you know, anybody can
13 calculate that.

14 If somebody asks me that
15 question, I can do the calculation. I go on
16 an FDA website. I would see the NDEA content
17 of what they report for Mylan. I could then
18 take that number and, you know, say over one
19 year what the cumulative exposure would be,
20 over two years, over three years, just as I
21 did with NDMA.

22 It's a trivial thing to do. I
23 didn't do it, but I could do it.

24 Q That was my first question.

25 (Simultaneous speech.)

1 (Reporter interrupted.)

2 A Sorry.

3 Q I asked him. I can't even
4 remember.

5 I think what I asked you is do
6 you intend to offer that opinion, and there
7 was an objection to form, and then the
8 witness was about to give an answer.

9 A And the answer was I don't intend
10 to, but if I was asked to, I would -- I could
11 do that.

12 Q Do you remember what exhibit that
13 was that you looked at earlier this morning
14 with the FDA numbers?

15 A I think the first few exhibits, you
16 took them back. Was it an early exhibit or
17 was it later?

18 Q It was early.

19 A I have it. Let me check. Let me
20 check I'm giving you the right thing. No,
21 sorry, it's not the FDA one. It's the
22 Torrent.

23 Q Well, do you want to go off the
24 record for a minute while we try to find the
25 exhibit?

1 I only have about ten more
2 minutes of questions, I think.

3 (Counsel conferred.)

4 THE VIDEOGRAPHER: Are we
5 going off the record?

6 MS. LOCKARD: No, we have it.

7 BY MR. TRISCHLER:

8 Q So Ms. Lockhard has been kind
9 enough to provide us with a chart that we've
10 been referencing, and you can see on page 2
11 of that chart, there is some data that was
12 provided with respect to Mylan.

13 Do you see that?

14 A I do.

15 Q So if you wanted to do the
16 calculation, let's take, for instance, the
17 highest level for Mylan reported on that
18 chart I think is .38 parts per million,
19 correct?

20 A In micrograms per tablet.

21 Q Okay.

22 And --

23 A And the level that you were asking
24 me about is -- the number in paragraph 35,
25 2520.

1 Q Correct.

2 A Okay. So it would take -- at that
3 level, it would take 6600 days to get to --
4 if you're consuming .38 micrograms a day of
5 Mylan -- of NDEA, it would take you 6,631
6 days to get to 2500 -- an exposure --
7 cumulative exposure of 2520, ignoring --
8 ignoring NDEA from diet and other sources,
9 just purely from that source.

10 Q And that's -- and that
11 2,520 micrograms is the LCE that you've
12 calculated for there to be a statistically
13 significant increase of pancreatic cancer?

14 A That's --

15 Q NDEA.

16 A As the Zheng study would suggest,
17 yes.

18 Q Okay. Thank you for that.

19 The -- and I guess just to
20 sort of wrap it up from my perspective,
21 Dr. Madigan, what I understood your testimony
22 to be is that you are not going to offer any
23 general causation opinions, correct?

24 A Correct.

25 Q What you are able to do and what --

1 the work that you did in this case was to
2 perform a statistical analysis on the
3 literature that was provided to you by
4 Dr. Etminan, correct?

5 A No.

6 MR. NIGH: Objection.

7 A So the -- this -- I was provided
8 with a list by Dr. Etminan which was a seed
9 list, if you will, so I consider lots of
10 other potential materials.

11 As it turns out, none of them,
12 you know, the set of studies that are
13 ultimately in Table 1 are the ones in
14 Etminan, as it happens.

15 Q So while you may have looked beyond
16 what was originally given to you in the list
17 created by Dr. Etminan, the studies that you
18 have -- that you ultimately utilize for your
19 statistical analysis are the same ones that
20 he provided to you?

21 A They were on his -- they're studies
22 that are on the list of references in his
23 report, as it happens.

24 Q And just to make sure my feeble
25 mind is able to understand it, what you're

1 testifying is -- is that you -- strike that.

2 You are not going to testify
3 that there's a statistically significant
4 increased risk of cancer from the
5 Valsartan-containing medications that were
6 provided by the defendants, correct?

7 MR. NIGH: Object to form.

8 A No. I mean, my analysis is -- is
9 about the association between NDMA and
10 various cancers as studied in dietary studies
11 and an occupational study.

12 Q Right.

13 So what you're going to say is
14 that you found statistically significant
15 increased risk of certain cancer types in the
16 literature that was initially provided to you
17 and then independently reviewed by you?

18 MR. NIGH: Object to form.

19 A I think that's basically correct,
20 yes.

21 Q And you -- you were asked about the
22 Pottegard study, and you gave us your
23 rationale for why it's not mentioned in the
24 report.

25 Did you ever review the Gomm

1 study?

2 A Not in English. So there was a
3 German version of it. I don't speak German.
4 So as I understand it, there's an English
5 version of it on the way, that's what I...

6 Q So it's fair to say you never read
7 the Gomm study?

8 A As I said, I don't read German, so
9 I didn't read it.

10 Q Just asking.

11 A I'm aware of the existence of it,
12 is what I'm trying to tell you, but, you
13 know...

14 Q I gathered.

15 A Yeah.

16 Q All right.

17 I think that might be all the
18 questions that I have. Thank you for your
19 time.

20 A Okay.

21 MS. LOCKARD: Are there
22 others?

23 MS. KAPKE: I have some, but I
24 can wait until after the manufacturers go.
25 This is Kara Kapke for CVS and Rite Aid.

1 MS. LOCKARD: Any of the other
2 manufacturers have questions?

3
4 EXAMINATION

5 BY MS. KAPKE:

6 Q Well, I -- this is Kara Kapke. I
7 represent CVS and Rite Aid. I just have a
8 couple of quick follow-up questions.

9 One of the things you
10 mentioned earlier in response to
11 Ms. Lockard's questioning was that you
12 believe that questionnaires are biased to the
13 null, and I just wanted to confirm that you
14 did not reference that in your report as an
15 opinion you're holding in this case.

16 Is that correct?

17 MR. NIGH: Object to form.

18 A No, that is not -- that is not
19 correct. Give me a second.

20 It's in paragraph 23, and
21 there's a reference in that paragraph.

22 Q Okay. That's -- that's fair.

23 And then I want to follow up
24 with a couple of questions based on
25 paragraph 35 where your report states that:

1 "Based on valsartan dosing, the levels of
2 NDMA reported in contaminated valsartan and
3 the time frame over which the contamination
4 occurred, it is scientifically plausible that
5 users of contaminated valsartan could develop
6 cancer."

7 I just want to confirm that
8 it's your opinion that you would agree that
9 not all, quote/unquote, users of contaminated
10 valsartan, as you put it, could develop
11 cancer.

12 Is that correct?

13 A Do I think that they're all going
14 to get cancer? No, but could any of them
15 get -- develop cancer? Yes.

16 Q Well, anybody who -- anybody could
17 develop cancer, true, whether they've taken
18 Valsartan-containing NDMA or not, correct?

19 A Sure. I -- I mean that, you know,
20 I do believe that everyone who takes
21 contaminated valsartan is at increased risk
22 based on -- based on what I have found in
23 these studies.

24 Q Okay. So that was the analysis
25 that I wanted to go to.

1 So is there a lifetime
2 cumulative exposure at which you believe NDMA
3 from valsartan will increase a person's risk
4 of cancer?

5 MR. NIGH: Object to form.

6 A So I don't know if I can be that
7 precise. I do have an opinion based on these
8 studies about, you know, LCEs from diet that
9 would seem to lead -- that are associated
10 with statistically significant increased
11 risk.

12 Also LCEs associated with
13 occupation exposure. I -- you know, I'm
14 assuming that ingesting NDMA or NDEA from
15 valsartan is no different.

16 Q Okay.

17 And that's why in paragraph 35
18 your preceding phrase to the sentence
19 discussing it's scientifically plausible that
20 users of contaminated valsartan references
21 valsartan dosing, NDMA levels and the time
22 frame, and why the next sentence references
23 daily use of valsartan containing
24 20 micrograms of NDMA for one year, correct?

25 A I'm sorry, I lost the drift of the

1 question there. Can you try again?

2 Q Sure.

3 So you -- in paragraph 35 when
4 you say it is scientifically plausible that
5 users of contaminated valsartan could develop
6 cancer, are you limiting that opinion, that
7 increased risk of developing cancer, to the
8 fact that you are basing that opinion based
9 on valsartan dosing, the levels of NDMA
10 reported in contaminated valsartan and the
11 time frame over which the contamination
12 occurred?

13 That's why you have those
14 qualifiers there.

15 A That's a for example. It's not a
16 qualifier. It's a for example.

17 Q Okay.

18 A So I didn't do that for other
19 contamination levels. I just --

20 Q Okay.

21 So --

22 A I just did for example.

23 Q So in your opinion, if a person
24 took a single pill of valsartan that contains
25 NDMA, would they be at an increased risk of

1 cancer?

2 A I don't have any such opinion one
3 way or another.

4 Q Okay.

5 So I will -- I'll ask that
6 your report -- the next sentence, for
7 example, you reference the NDMA from
8 valsartan would be less than 700 -- or 7300
9 micrograms?

10 A I'm not --

11 Q Do you see that, where you're
12 talking about the Hidajat study?

13 A 7514 -- you're not -- sorry, you're
14 in paragraph 34 now?

15 Q Yeah.

16 And that's basically
17 20 micrograms of NDMA daily for one year,
18 correct?

19 MR. NIGH: Object to form.

20 A No. I'm sorry, I'm not -- I'm not
21 following your logic here.

22 So Hidajat was exposure via
23 inhalation.

24 Q Okay.

25 So I'm going to ask, what

1 would 20 micrograms of NDMA daily for one
2 year be in terms of a lifetime cumulative
3 exposure?

4 MR. NIGH: I'm going -- at
5 this point, I'm going to put on the record
6 that I believe that the questioning is
7 becoming cumulative.

8 I believe we're getting into
9 areas that have been addressed, and, you
10 know, I'll let this go on for a few more
11 questions, but I would put a strict, harsh
12 warning that at this point it's cumulative.

13 We have a report that is ten
14 pages long. We have spent hours and hours
15 and hours, and now we have a third questioner
16 that -- where I think the questions are
17 becoming more and more cumulative as we go
18 on.

19 Go ahead.

20 A Does paragraph 29 answer your
21 question?

22 BY MS. KAPKE:

23 Q I don't know, but I am asking you
24 to answer my question.

25 What would 20 micrograms of

1 NDMA daily be in terms of a lifetime
2 cumulative exposure?

3 You would derive that by
4 multiplying 20 micrograms by 365 days,
5 correct?

6 A To get the exposure in that one
7 year, right.

8 Q Right.

9 If you -- if you only took
10 valsartan for one year that contained NDMA
11 and the NDMA, using your assumption,
12 contained 20 micrograms a tablet, you would
13 have an LCE of 7300 micrograms, correct?

14 A Sure.

15 Q Okay.

16 Seventy --

17 A Let me be more careful there.

18 You -- from that source in
19 that one year, your cumulative exposure would
20 be 7300.

21 Q Okay.

22 And that is what you say is --
23 you say that both Hidajat and several dietary
24 studies show statistically significantly
25 elevated risks of several cancers in the next

1 sentence in paragraph 35 of your report,
2 correct?

3 I'm trying to draw a link
4 between those two statements.

5 A I see. So 20 -- 20 micrograms a
6 day for a year is -- yeah, gets you to 7300.
7 7300 is larger than many of the lifetime
8 exposures in Table 1 for which there is
9 statistical significance. It's just shy of
10 the same number in Hidajat.

11 Am I answering your question?

12 Q Yes.

13 And what I'm trying to get you
14 to explain here is I think using your
15 analysis, you -- in the language of your
16 report, you have a person needing to take
17 valsartan that contained NDMA of an average
18 of 20 micrograms for at least one year in
19 order to have an increased risk of cancer.

20 Is that fair?

21 A No, that's not what I said.

22 Q Okay.

23 And what I'm trying to figure
24 out -- and I don't think this has been asked
25 and I don't think you've explained that -- is

1 where in your report you explain that that's
2 not the case, that it doesn't have to be at
3 least one year of taking a tablet containing
4 20 milligrams -- 20 micrograms of NDMA for at
5 least a year?

6 A So look at Table 1. So Table 1
7 shows the lifetime cumulative exposure, you
8 know, in those studies. And for several of
9 them, it's statically significant at well
10 under 7300.

11 Q Okay.

12 So what's the lowest that
13 you're willing to go?

14 A 2338 in --

15 MR. NIGH: Object to form.

16 A 2,338 -- an LCE of 2,338 micrograms
17 in Goodman yields a statistically significant
18 increased risk of lung cancer.

19 In -- there you go. That, I
20 think, is the -- no. It's also, I believe,
21 statistically significant in Keszei for
22 squamous cell esophageal cancer in women at a
23 lower -- at a lower LCE. I think that's --

24 Q Okay. Okay.

25 So is it fair to say, then, if

1 you're relying on an assumption that each
2 tablet of valsartan contains 20 micrograms of
3 NDMA, that you need at least 100 pills of
4 valsartan containing NDMA before you have an
5 increased risk of cancer?

6 A Absolutely not.

7 MR. NIGH: Object to form.

8 A But what -- what is true is, you
9 know, per these studies, the smallest
10 lifetime cumulative exposure that yields a
11 statistically significant increased risk --

12 (The deponent read the
13 document.)

14 A I misspoke. It's actually 1962,
15 actually. It's the lowest -- and it happens,
16 that's the lowest one for which there's a
17 statistically significantly increased risk.

18 Q Okay.

19 So -- so tell me the basis
20 that you have to suggest that there's an
21 increased risk of cancer for a person with a
22 lifetime cumulative exposure to NDMA that is
23 less than 1962 micrograms.

24 A I never said any such thing. I'm
25 not following -- I don't follow the question.

1 Q Okay.

2 Then -- okay. So will you
3 agree that there is no increased risk of
4 cancer for a person with a lifetime
5 cumulative exposure of NDMA that is less than
6 1962 micrograms?

7 MR. NIGH: Object to form.

8 A No, no. Absolutely not. I would
9 not agree with that statement.

10 Q Okay.

11 Then what basis do you have to
12 not agree with that statement?

13 A There are increased risks at
14 various levels that this -- the level that
15 yields statistical significance -- the lowest
16 level that yields statistical significance in
17 these studies is 1962, but that absolutely
18 doesn't mean there isn't an increased risk at
19 much lower -- at potentially much lower
20 levels.

21 Q Okay.

22 So what is a scientifically
23 valid opinion that there is an increased risk
24 that is not based on chance when you have an
25 LCE to NDMA less than 1962?

1 A We read the FDA's statement on
2 p-values a few minutes ago, and it's not the
3 same as due to chance. It's a completely
4 different concept. So the way you're
5 phrasing it there is kind of inappropriate.

6 Like I said, based on these
7 studies, there is statistical significance,
8 for what that's worth -- because that's what
9 you were asking about earlier.

10 There's a statistical
11 significance with an LCE as low as 1962.
12 Statistical significance.

13 You know, is there increased
14 risk at levels lower than that, I would have
15 to go back and look at the studies one by one
16 to see if they are -- if there is.

17 But it wouldn't be -- it
18 wouldn't be statistically significant. That
19 doesn't mean there isn't an increased risk.

20 Q Okay.

21 Do you have any basis to
22 suggest that there is a statistically
23 significant increase in risk of cancer for a
24 person with a lifetime cumulative exposure to
25 NDMA that's less than 1962 micrograms?

1 A In the studies I looked at, the
2 lowest lifetime cumulative exposure that
3 yielded a statistically significant increase
4 was 1962, I believe, although that might
5 be --

6 I'd have to go back and look
7 at Keszei for esophageal squamous cell
8 cancer, which for women there is a lower
9 lifetime cumulative exposure there.

10 So I'd need to go back and
11 look at that more closely.

12 Q Okay.

13 So 1962 micrograms of NDMA, to
14 get that type of exposure from valsartan that
15 contained NDMA using your assumption of
16 20 micrograms per tablet, would you have to
17 take 98 pills, correct? At least 98 pills?

18 A I don't know. Let me do the math.

19 As a matter of fact, to get to
20 1962 micrograms from valsartan alone at
21 20 micrograms a pill, yes, it would take 98.1
22 days. Call that 99 days.

23 Q Okay.

24 A To get to that level. That's a
25 fact, yes.

1 Q Okay.

2 On what basis do you have to
3 assert that there is an increased risk of
4 cancer from taking pills containing --
5 valsartan pills containing NDMA for fewer
6 than 99 days?

7 MR. NIGH: Object to form.

8 A Well, first of all, you're equating
9 statistical significance with the existence
10 of risk. That's inappropriate. So I can
11 tell you that statistical significance -- if
12 that's what you're interested in, statistical
13 significance occurs at an LCE of 1962.

14 If you're -- if you're -- from
15 valsartan alone, if it's 20 micrograms in the
16 pill, yes, it's 99 days. But as we looked at
17 earlier, for all I know, it could -- even --
18 there's a document suggesting that it can be
19 a lot more than that that we looked at this
20 morning.

21 So I -- you know, I don't
22 know. It all depends on how much NDMA is in
23 the pills. I do not know how much NDMA is in
24 the pills.

25 Q Okay. Those are all the questions

1 I have.

2 A Thank you.

3 MS. LOCKARD: Anyone else? I
4 don't have any more questions for you.

5 THE DEPONENT: Okay. Are we
6 done?

7 MR. NIGH: I don't have any
8 questions. I think we're done. We'll read.

9 THE DEPONENT: Very good.
10 Thank you pleasure to meet you.

11 MS. LOCKARD: Nice to meet
12 you, too. Enjoy your dinner.

13 (Discussion off the record.)

14 THE VIDEOGRAPHER: Hold on.
15 Let me go off the record.

16 The time is 4:40. That
17 concludes the deposition. We're off the
18 record.

19 (Whereupon, the proceedings
20 adjourned.)

21

22

23

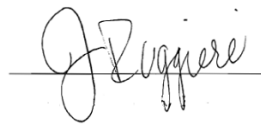
24

25

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C E R T I F I C A T E

I, Jill K. Ruggieri, Registered Merit Reporter and Certified Realtime Reporter, do certify that the deposition of DAVID MADIGAN, PhD, in the above-captioned matter, on August 5, 2021, was stenographically recorded by me; that the witness provided satisfactory evidence of identification, as prescribed by Executive Order 455 (03-13) issued by the Governor of the Commonwealth of Massachusetts, before being sworn by me, a Notary Public in and for the Commonwealth of Massachusetts; that the transcript produced by me is a true record and accurate record of the proceedings to the best of my ability; that I am neither counsel for, related to, nor employed by any of the parties to the above action; and further that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.



Jill K. Ruggieri, RPR, RMR, FCRR, CRR

Transcript review was requested of the reporter.

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1 Daniel Nigh, Esq.

2 dnigh@levinlaw.com

3 August 11, 2021

4 RE: In Re: Valsartan, Losartan, Et Al v.

5 8/5/2021, David Madigan , PhD (#4748772)

6 The above-referenced transcript is available for
7 review.

8 Within the applicable timeframe, the witness should
9 read the testimony to verify its accuracy. If there are
10 any changes, the witness should note those with the
11 reason, on the attached Errata Sheet.

12 The witness should sign the Acknowledgment of
13 Deponent and Errata and return to the deposing attorney.
14 Copies should be sent to all counsel, and to Veritext at
15 erratas-cs@veritext.com

16
17 Return completed errata within 30 days from
18 receipt of testimony.

19 If the witness fails to do so within the time
20 allotted, the transcript may be used as if signed.

21
22 Yours,

23 Veritext Legal Solutions
24
25

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1 In Re: Valsartan, Losartan, Et Al v.

2 David Madigan , PhD (#4748772)

3 E R R A T A S H E E T

4 PAGE_____ LINE_____ CHANGE_____

5 _____

6 REASON_____

7 PAGE_____ LINE_____ CHANGE_____

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18 REASON_____

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20 _____

21 REASON_____

22 _____

23 _____

24 David Madigan , PhD

Date

25

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1 In Re: Valsartan, Losartan, Et Al v.

2 David Madigan , PhD (#4748772)

3 ACKNOWLEDGEMENT OF DEPONENT

4 I, David Madigan , PhD, do hereby declare that I
5 have read the foregoing transcript, I have made any
6 corrections, additions, or changes I deemed necessary as
7 noted above to be appended hereto, and that the same is
8 a true, correct and complete transcript of the testimony
9 given by me.

10
11 _____
12 David Madigan , PhD

_____ Date

13 *If notary is required

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[& - 2018]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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